THE OSHA CANCER POLICY:
GENERIC VS. SUBSTANCE-SPECIFIC REGULATION
IN AN AREA OF SCIENTIFIC UNCERTAINTY

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SUMMARY

During the late 1970's, the Occupational Safety and Health Administration (OSHA) and several other government agencies developed a policy intended to permit more rapid regulation of cancer-causing substances. The existing method of regulating carcinogens one-by-one is inadequate due to the long time spans encountered before, during, and after rulemaking. Such delays are caused by extensive staff preparation time for each substance, litigation, economic impact analysis, and quantitative risk assessments. This thesis examines the social context of regulation of carcinogens, an historical analysis of the developments at OSHA that led to the policy's formulation in 1980 and the subsequent decision not to implement it, and a review of a number of philosophical and methodological dilemmas posed by economic and risk analysis of carcinogen regulation. A case study of how methylene chloride would have been regulated under the policy (had it been fully implemented) is provided to illustrate the differences between generic and substance-specific regulation. The number of cancer cases which could have been prevented by generic regulation of this one chemical is estimated. Interviews with former President Jimmy Carter, the last four OSHA administrators, personnel at NIOSH, OSHA, NTP, OMB, and other key individuals were conducted. Historical documents at the Jimmy Carter Library in Atlanta, Georgia were also analyzed. Conclusions include:

1. The necessity of a generic policy
2. The identities of the stakeholders involved
3. The inadequacy of the dominant model separating risk management from risk assessment
4. The hegemony of economists and risk assessors in modern occupational cancer regulation
5. The absence of organized labor
6. How public input into the decisionmaking process can be improved by implementation of a generic cancer policy.

CHAPTER I

INTRODUCTION

Generic Regulation and the Incremental Norm

Motivated largely by increasing production, modern society is marked by rapid rates of technological innovation previously unimaginable. With these changes has come a recognition of the need to plan for various consequences, some well-defined and others less clear. One school of thought has argued that such planning is comprehensible only in small packages, and that our political system is capable of nothing more extensive than a "muddling through" approach.[1] Others have noted the inadequacies of this approach, calling for a more "comprehensive, rational" planning stance, stretching our prescient abilities to the utmost.[2]

The massive introduction of synthetic chemicals into commerce after World War II is a classic example of rapid technological innovation unaccompanied by a comprehensive social policy. However, the recognition of the need for public policy planning arrived some years later, and came only after reports of harmful environmental and human health effects.[3] The first attempts at muddling through soon followed. While the magnitude alone of these changes would seem to make the need for a comprehensive social policy self-evident, regulation of these substances has in fact more closely resembled a slow, one-by-one approach, i.e. the "muddling

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[1]Lindblom, CE: "The Science of Muddling Through," Public Administration Review, Spring, 1959, p. 79-88

[2]Quade ES: Analysis for Public Decisions, North Holland Press, New York, 1982

[3]Many environmentalists cite the publication of Rachel Carson's book, Silent Spring, Fawcett Publishers, Greenwich, Conn, 1962 as the first time the issue was raised publicly.

through approach." At the same time, there have been a few occasions when abrupt, large-scale changes in policy have been effected. The Occupational Health and Safety Act (OSHA)[4] of 1970 was such a change. It has been described as a new right added to the Bill of Rights, although it is really a legal right, not (yet) a constitutional right. In the words of a former Assistant Secretary of Labor for OSHA, it is "the right to a safe and healthful workplace."[5] In short, the formation of OSHA was an attempt by Congress to implement a comprehensive policy; unfortunately, the agency has remained mired in the norm of incrementalism for most of its brief history.

Various attempts have been made to speed up the process of regulation to meet the needs of a complex technological society. The clash between a widely-perceived need to act more quickly and the struggle actually to do so is vividly illustrated by OSHA's attempt to regulate cancer-causing substances (carcinogens) in the nation's workplaces. The cancer policy, officially known as the "Regulation Covering the Identification, Classification, and Regulation of Potential Occupational Carcinogens,"[6] is designed to regulate certain chemicals as a group. The generic approach is broad in scope, covering a number of individual substances which produce similar health hazards, and addressing issues "at the frontiers of science" where scientific knowledge is incomplete and uncertain. The cancer policy contained principles defining how OSHA would use such knowledge to protect

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[4]"OSHA" refers to both the Occupational Safety and Health Act and the Occupational Safety and Health Administration in this thesis.

[5]Morton Corn, quoted in "Policies, Objectives and Plans of OSHA," ABA National Institute on Occupational Safety and Health Law, 1976, p. 229, cited in Women's Occupational Health Resource Center (WOHRC) News, September 1987, p. 7

[6]45 Federal Register (FR) 5002, Jan. 2, 1980

worker's health, thus avoiding duplication of efforts for each newly-identified carcinogen facing regulation.

The Enforcement Approach vs. The Guideline Approach

While other federal agencies have acted to address cancer hazards, the OSHA policy has been the center of a storm of controversy throughout its history. Partly, this is due to the fact that, in its 1980 formulation, the policy is one of the few that are legally-enforceable. It is a formal rule which forces OSHA to take certain actions based on certain information. For example, it could ban the production of a carcinogen if substitutes were available. The Food and Drug Administration's tight regulation prohibiting addition of carcinogens into food under the Delaney clause is the only other truly legally-enforceable cancer policy. Other agencies have for the most part opted for a "guideline" approach which delineates internal agency methods, but does not immediately affect commerce. The Environmental Protection Agency (EPA) and the Office of Science and Technology Policy (OSTP) have developed such guidelines recently,[7,8] and are likely to define government policy in this area in the immediate future. Supporters of the guideline approach argue that it can keep pace best with changes in scientific understanding. Critics charge that guidelines are ineffective in actually leading to control of hazards and the "teeth" of legal enforcement are a necessity.

Risk Management and Risk Assessment

Enforcement policies and guidelines share a common denominator: they both explain the assumptions the agency will make in areas where uncertainties are

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[7]EPA: "Environmental Protection Agency Guidelines for Carcinogen Risk Assessment," 51 (FR) 33993, September 24, 1986

[8]OSTP: "Office of Science and Technology Policy Guidelines on Assessing Chemical Carcinogens," 50 FR 10372, March 14, 1985

plentiful. Typically, risk assessment and risk management have been depicted as "scientific " and "political" endeavors, respectively. However, the history of the OSHA cancer policy shows that there is much overlap between the two. The political values of the various actors are as important as the scientific understanding of the problem. As we shall see, history is replete with instances of how the two combine to produce policy.

The Use of Scientific Information by Industry and Labor

More fundamentally, the turbulence surrounding the cancer policy is a reflection of the history of OSHA itself and the history of labor relations in this country. The decision to put the agency in the Department of Labor instead of in the Public Health Service or some other scientific agency was a recognition of the political nature of occupational health and safety regulation. The respective responsibilities and needs of private employers and workers often have been the scene of sometimes violent upheaval and conflict. Both organized labor and industry have used scientific information to serve their own needs.

For example, the first documented evidence of occupational cancer was made by Sir Percival Pott in 1775, who identified coal soot as the cause of skin and scrotal cancer in chimney sweeps. Two years later, the Danish Chimney Sweepers Guild demanded better protective clothing and a daily bath as part of their organizing efforts, based on Pott's findings.[9]

Since then, the 19th century notion that workers had "freely contracted" to bear occupational risks when taking on a job[10] has given way to government-

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[9]Williams, LR: "Work and Health Around the World," American Industrial Hygiene Journal, December, 1987, p. A-784

[10]Horowitz, MJ: The Transformation of American Law, 1780-1860, Harvard University Press, Cambridge, 1977

regulated worker's compensation laws, which place some responsibility for occupational risks on the employer.[11]

When the policy was first adopted in 1980, then-Assistant Secretary of Labor for OSHA Eula Bingham, a supporter of organized labor, declared it to be "...a course that will profoundly affect the quality of life for hundreds of thousands, if not millions, of American workers."[12] Secretary of Labor Ray Marshall characterized previous attempts at regulating individual carcinogenic substances as "...trying to put out a forest fire one tree at a time."[13]

On the other hand, some regard the OSHA cancer policy as the epitome of what is wrong with attempts to use scientific research to set social policy. For instance, Edith Efron has nothing good to say about the preamble to the policy: "It has no identified author. It is long; it is extremely technical; it is chaotically organized; it is printed in agonizingly small type; it is badly written; it is pedantic, pompous, and repetitious. It even succeeds, somehow, in being simultaneously polemical and boring. It is a wretched piece of literature." [14] Yet even she states that the views contained in this policy are "particularly worthy of inspection." The American Industrial Health Council, an industry organization, believes that the policy must be firmly grounded in "sound science," although critics charge that is a euphemism for delay. The policy is intended to address issues that are currently beyond firm scientific understanding. Although scientific knowledge plays an important role in setting the boundaries, differences in social and economic views,

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[11]Berman, DM: Death on the Job, Monthly Review Press, New York, 1978

[12]Eula Bingham's Remarks on the OSHA Carcinogen Policy, in Kitty Bernick's Papers at the Jimmy Carter Library, Box 10, OSHA Carcinogen File

[13]Quoted in Bingham E: "Nothing to Lose But Your Lives," The Sciences, July/August 1979, p. 30

[14]Efron E: The Apocalyptics, Simon and Schuster, New York, 1984, p. 220

values, and political philosophy are key in understanding how a generic cancer policy can be implemented at OSHA.

The Public Fear of Cancer as the Motivation for a Generic Cancer Policy

While some dilution of concern has occurred as a result of the epidemic of Acquired Immune Deficiency Syndrome, cancer still remains one of the most feared and pervasive of all modern diseases. Cancer mortality has increased approximately 250 percent over the last 50 years.[15] Those who suffer include not only the victim, but also the survivors, for example, family members who must struggle to maintain some quality of life while a loved one slowly succumbs. The specific causes and mechanisms of cancer induction are still murky (despite substantial progress) and are probably numerous, making it difficult to conclusively prove causation by individual substances. In addition, there remains substantial uncertainty regarding cancer incidence trends. Are there more cancers appearing in all age groups, or is cancer merely a natural reflection of an aging population? Fear generated by the unknown and the uncertainties thus plays an important role. In addition, few would deny the role of the media in keeping the question of cancer fresh in the public mind.

Modern and Traditional Risk

Is the fear justified? The risks posed by exposure to carcinogens and other products of modern technology are different from older, more traditional risks. Of course, both risk and cancer have always been present, and as industry is quick to

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[15]Devessa SS, Schneiderman MA: "Increase in the Number of Cancer Deaths in the U.S." American Journal of Epidemiology Vol. 106, 1977, p. 1-5

point out, obtaining a risk-free world is neither possible nor desirable.[16] But risks in technologically advanced societies are fundamentally different from those in more traditional, less developed societies. For much of the developing world, the risk of starvation, infectious disease, exposure to the elements, etc. are still of paramount concern, as they have been throughout human history. However, modernized nations have been able to eliminate many of these types of risks, at least for the majority of their populations.

Instead, more long-term risks have taken their place. While the chances (i.e., probability) of an adverse consequence may have been reduced, the extent of those consequences, should they actually occur, has greatly increased. In short, there has been a shift from limited, short-term risks to catastrophic long-term ones. For example, increased food production has been made possible, at least in part, from the increased use of agricultural chemicals, such as pesticides, fertilizers, etc. At the same time, some of these chemicals are known to be capable of causing mutations and cancer in test animals. If one accepts the central tenant of the theory of evolution, which holds that new forms emerge through mutation, then it is not inconceivable that the ubiquitous introduction of synthetic chemical substances may have already affected the very course of evolution in ways that will be difficult, if not impossible, to detect (i.e., what is a "normal" course of evolution?). Thus, the potential risks associated with cancer reside not only with the immediate victims, but with the shape of our collective future. This means that quantitative risk assessments, which estimate the number of cancers produced by

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[16]Cox GV: "Risk is Normal to Life Itself," Paper delivered at American Industrial Hygiene Conference, 1987. The author is vice president of the Chemical Manufacturers Association. "We live in a society that expects technology to provide a risk-free utopia. As we all know, utopias do not exist, and energies spent trying to reach an unrealistic goal are spent in vain...We should strive to reduce risks to a level that reaches toward zero, but any attempt to actually try to reach absolute zero will mean misspent resources."

exposure to a particular chemical, may underestimate its true impact, even if the normal conservative assumptions and safety factors are used.

The context of petrochemical introduction into our society has been described by Barry Commoner, a leading biologist, this way:

> During the course of evolution, organic chemistry has been restricted to a narrow range of possible compounds. What the petrochemical industry did was to break out of those limits. In the natural world, organic chemistry is the outcome of a very long evolution...incompatible compounds have been eliminated. In my opinion, an organic compound that does not now occur in living things has to be regarded as an evolutionary reject. Simply put, somewhere down the line a few billion years ago, perhaps some cell got it into its head to synthesize dioxin [a highly toxic substance] and has never been heard from since...We keep being surprised that chemicals that were perfectly nice and simple to make turn out to have very serious biological consequences.[17]

In short, the stakes have become much higher. The dimensions of the failure to plan comprehensively for such scenarios are still unfolding. Carcinogens, in this view, are merely one of several types of substances that are active through DNA-related mechanisms, substances that in theory are capable of posing extensive, but not highly probable, adverse outcomes.

Of course, the alternative view (that the fear is not justified) is just as plausible. In this argument, the risks posed by synthetic chemicals pale in significance when compared to "natural" carcinogens found in the diet, smoking, and other more voluntary lifestyle habits.[18] In fact, a major conference held at the Jimmy Carter Center of Emory University in 1984 concluded that tobacco is the leading single cause of premature death in the U.S. population.[19] Furthermore, a former

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[17]Commoner B: "High-risk High Tech: Who Decides How It Is Used?" Science for the People, March/April 1987

[18]Ames BN, Magaw, R, Gold, LS: "Ranking Possible Carcinogenic Hazards," Science, Vol. 236, April 17, 1987, p. 271-280. "...carcinogenic hazards from current levels of pesticide residues or water pollution are likely to be of minimal concern relative to the background levels of natural substances..."

[19]Closing the Gap: The Burden of Unnecessary Illness, Edited by Robert W. Amler and H. Bruce Dull, Oxford University Press, New York, 1987, p. 188

official of the Centers for Disease Control has said that tobacco will cause more deaths worldwide than all other causes by the turn of the century, although not all of these will be due to cancer alone.[20] The effect of this view may be that in order to get the "biggest bang" for the regulatory buck, priority needs to be given to those risks that are, relatively speaking, the most easily detected and for which certainty is highest.

While this study focuses on carcinogens in occupational settings, it should be clear that the potential risk posed by toxic substances goes well beyond either cancer or the workplace. Reproductive problems, mutations, immunological sensitization caused by environmental as well as occupational exposures are also important parts of the risk equation. In fact, some have argued that cancer has occupied the center stage to the detriment of research into these other areas.[21] One economist has suggested that regulation of toxic chemicals has resulted in less attention to safety hazards, which may in fact pose higher risks.[22] While the data for many safety hazards are much less uncertain than those for health hazards, this should not necessarily mean that regulation should proceed only in those areas where a high level of certainty exists. How much do we need to know before regulating? And how should society use uncertain knowledge when lives are at stake?

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[20]Personal Interview with Jimmy Carter, Emory University, Nov. 12, 1987. "Dr. Foege believes that by the year 2000, the number one cause of premature death in the entire world will be from cigarettes."

[21]Silbergeld, E: "Risk Assessment," letter in Science, September 18, 1987. "Discussion of risk assessment...continues to confine our national debate to one end point--cancer risk. While evaluating the potential risks of chemicals as carcinogens is important, the human disease and dysfunction that can reasonably be associated with impacts of chemical exposure and environmental modifications are likely to be expressed in many other outcomes."

[22]Morall, John F. III: "A Review of the Record," Regulation, November/ December, 1986, p. 25-34

The assessment of whether exposures to carcinogens, mutagens, teratogens, and other substances is truly of catastrophic dimensions is not likely to be resolved soon. Irving Selikoff, a leading cancer researcher, has pointed out that this controversy has been around since at least 1895, when

> ...Rehn reported the first three cases of cancer of the bladder among aniline workers. When additional cases of this association were identified in the next 15 years in Germany and Switzerland, it was projected that the developing chemical industry, with its increasing number of synthetic chemicals new to the human environment, would bring with it a host of problems and an unhappy harvest of cancer. This prediction, in the next few decades, seemed far from unreasonable when our laboratory colleagues demonstrated carcinogenicity of literally hundreds of chemicals in animal test programs. Yet, by and large, the prophecy was not seen to be fulfilled in the first half of the 20th century...Thus, until recent years we were faced with something of a paradox; Rehn and his contemporaries had shown that human cancer could result from chemical industry exposure, laboratory studies indicated that the agents could be varied and numerous, yet human experience had not demonstrated this to be a major problem...Do experiences with vinyl chloride, bischloromethyl ether, chromates, etc., demonstrate that the prophecies were really correct, or merely premature?[23]

Eighteen years later, gaps in the scientific knowledge are still likely to be with us for the foreseeable future, in spite of some very promising advances. The methylene chloride case study examined here shows that even with a better understanding of pharmacokinetic data (how chemicals are absorbed, transported, distributed, transformed, and excreted from the body) and the extrapolation of animal testing data to humans, assumptions are still necessary, and in some respects, even more uncertain.

To Act Or Not To Act: That Is The Question

How can a regulatory agency like OSHA confront the issue of scientific uncertainty and still fulfill its mandate? Congress defined that mandate to "...assure

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[23]Selikoff, Irving: "Perspectives in the Investigation of Health Hazards in the Chemical Industry," Proceedings of the Meeting of the Scientific Committee, Carlo Erba Foundation, Occupational and Environmental Health Section, Milan, December 12, 1975

so far as possible every working man and woman in the Nation safe and healthful working conditions."[24] Furthermore, OSHA is required to ensure that an employer "...furnish to each of his employees employment and a place of employment free from recognized hazards."[25]

The relationships that develop among the actors in the OSHA cancer policy-making process--scientists, decisionmakers, policy analysts, economists and lawyers--are key to understanding how scientific uncertainty is treated. At this date, few would be surprised to learn that values and policy judgments play a key role, not only in the political considerations present in every policy formulation, but also in the scientific assessment of carcinogens.[26] In fact, the conflict among various social groups is increasingly played out in the scientific realm, not the political arena. It is often easier to argue that a particular animal study is deficient in some technical respect, than it is to argue that one ought to be more tolerant of or more averse to imposing risks on moral grounds.[27] Sadly, such moral investigation appears to be regarded as a deadend, not amenable to "rational" examination, even though ethical decisions by government are the foundation of democracy. Whether or not inferences are explicitly delineated during the phase of scientific assessment does not change the fact that public involvement and our democratic ideals are proscribed by the very technical nature of the debate. Thus, science is, on one level, a political tool wielded by various players for political ends. We shall see that the substance of the OSHA carcinogen policy is shaped in large measure by how science, or more precisely, the gaps in scientific knowledge, are used to make

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[24]OSHA Act, Public Law 91-596, Section 2(b)

[25]Ibid. Section 5(a)(1)

[26]Personal Interview with Morton Corn, February 8, 1988

[27]Personal Interview with Anson Keller, December 16, 1987

assumptions which either favor or place at additional risk employers and workers, respectively.

Yet there is something profoundly disquieting about this seemingly opportunistic and selective use of science by various advocacy groups. The positivist desire to know things with certainty, to find the truth, plays an important role in the ultimate decision to classify a particular substance as carcinogenic. Unfortunately, this certainty is, practically speaking, possible only in human epidemiological studies, which measure the damage after it has occurred. This is clearly an unacceptable basis to formulate public policy, since action is taken only after it is too late. Nevertheless, most OSHA health standards have in fact been developed in response to human data, not animal testing.[28] The failure to act on animal data poses a significant moral dilemma for modern society.

Plausibility and the Changing State of Knowledge

What standard of scientific proof should be used to act? One former OSHA administrator commented that "good science is needed to make good regulations."[29] In other words, the state of scientific knowledge places bounds on the terms of the debate. Whether one wishes to make risk-tolerant or risk-averse assumptions in the scientific assessment, they must be plausible and consistent with the scientific knowledge as it exists at a given moment in time. Of course, since scientific knowledge is continually changing, the bounds of the public debate also change. This mix of plausibility, political values, and scientific information forms the cornerstone of cancer policy from one administration to the next.

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[28]Identifying and Regulating Carcinogens: Background Paper, Office of Technology Assessment, Congress of the United States, US Government printing Office, Washington, DC, 1987, p. 77-85

[29]Interview with Eula Bingham, September 9, 1987

For some, such unambiguous scientific evidence is the only useful evidence for regulatory purposes. For others, certain preliminary indications of carcinogenicity are enough to act, since lives may be at stake. In their guidelines for risk assessment of carcinogens, the Office of Management and Budget argues that the compounding of conservative assumptions typically used by environmental regulators leads to wholly unrealistic estimates of human cancer incidence which are simply not believable.[30] On the other hand, the 1980 OSHA cancer policy required only two positive animal studies to permit a determination of potential carcinogenicity.

Of course, history is full of failures to act quickly enough. Arsenic was once widely thought not to be a carcinogen, since there are no animal studies to support such a finding. Human evidence has shown that the substance is in fact capable of producing tumors. Thalidomide caused deformities in 20,000 children,[31] even though it had been tested in several different animal species prior to release. Beta-naphthylamine caused bladder cancer in a large percentage of exposed workers, far more than would have been predicted by animal studies.[32] Even the now well-known association regarding cigarette smoking, asbestos and cancer was unproven for many years.

How Tension Among Scientists, Decisionmakers, Lawyers, and Policy Analysts Can Lead To Action

Some have argued that when regulation has been left solely to scientists, there has been a general failure to regulate, since scientists are trained to act only on the basis of nearly absolute proof. The scientific agencies in the old Health,

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[30]"Regulatory Program of the United States Government", April 1, 1986-March 31, 1987, Office of Management and Budget, 1987, p. xix-xxvi

[31]Dr. Peter G. Gerone, quoted in Feder BJ: "Beyond White Rats and Rabbits," New York Times, February 28, 1988, p. F8

[32]Personal Interview with Eula Bingham, Ibid.

Education and Welfare department failed to regulate toxic substances until Congress forced the issue in the early seventies. Since science is disputatious, scientists do not tend to act on uncertain data. Rather, they formulate further experiments to reduce the uncertainty. Thus, tension between scientists seeking additional data and those wishing to take more immediate action develops. However, the tension created between scientists and decisionmakers is not necessarily competitive, but can be creative. The OSHA cancer policy as it was originally formulated in 1980 was the result of close cooperation between cancer scientists, lawyers (and other policy analysts), and public decisionmakers (Morton Corn and Eula Bingham), and should serve as proof that the "comprehensive rational" approach is indeed within grasp.

How Economic and Quantitative Risk Analysis Can Lead To Paralysis and a Retreat from Democracy

How has economic analysis, such as cost-benefit analysis, shaped our concept of what is feasible in attacking occupational cancer? Of course, the economic impact of the cancer policy is potentially quite large. During the Carter administration, the Council on Wage and Price Stability estimated that moderately strict standards for all 2415 known or suspected carcinogens would eventually cost $526 billion.[33] Former President Carter has stated that he thought it was important to force his regulators to work with his economic advisors,[34] even though this often led to bitter conflict. Whether this tension is productive or not is more problematic than the relationship among scientists, policy analysts, and decisionmakers. As we shall see, there are fundamental ethical difficulties and

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[33]Noble C: The Rise and Fall of OSHA, Temple University Press, Philadelphia, 1986, p. 19

[34]Interview with Jimmy Carter, Ibid.

other shortcomings in modern economic theory which may tend to stifle creative solutions to the cancer regulatory problem. These dilemmas include:

1. The pricelessness of human life vs. the knowledge that regulatory expenditures do in effect place a price on our heads.
2. Whether individual decisionmaking (the foundation of modern microeconomics) can be used as a basis for social decisionmaking.
3. Equity

Similarly, the use of quantitative risk assessments, now widely acknowledged to be a necessary ingredient in policy decisions, may at the same time tend to obscure more important concerns among the citizenry, namely, fairness, control, and trust of experts.

Lessons From The History Of The OSHA Cancer Policy

How Carter's OSHA Used "Regulatory Reform" to Develop the Cancer Policy

Former OSHA Administrators, Congress, and other investigators have viewed the paucity of health standard development at OSHA with increasing concern.[35] From 1972-86, OSHA issued health standards covering only 22 carcinogens. Fourteen of these were adopted in one rule in the early seventies when OSHA was still quite young. Two others, benzene and formaldehyde, have recently been finalized. The benzene standard development process is especially noteworthy. With numerous court challenges, it has taken more than a decade to be finalized. The recent OSHA formaldehyde standard has taken nine years from the time when the

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[35]Morton Corn, Eula Bingham, Thorne Auchter, and Patrick Tyson, all former head administrators (Tyson was acting administrator for a short time), expressed disappointment with the slow pace of health standard development during individual interviews. The issue is also expected to receive attention in Congressional Oversight hearings this year (see "OSHA Faces Rigorous Congressional Oversight," by Stephen G. Minter in Occupational Hazards, September 1987, p. 95-99

first animal studies showing carcinogenicity appeared in 1978, and final promulgation in December, 1987. Further court action is likely for the formaldehyde standard.

Why the concern over such a slow pace? Isn't informed, deliberate rulemaking with judicial review a good thing in a democracy? Shouldn't we take the time to consider all viewpoints? In hearings before the Senate in 1977, it was reported that 21,000 chemicals were in common use and were known to be toxic. Of these, 2,400 were suspected of causing cancer. It was estimated that there were more than 100,000 deaths from occupational diseases, and another 390,000 new cases of occupational disease annually, although not all of these were due to cancer.[36] More recently, the National Research Council looked at testing needs for toxic substances. Taking a randomized subset of all chemicals in use, the study concluded that, in order to form a complete health hazard assessment, virtually all chemicals in commerce needed additional toxicological testing. Only 27% of the chemicals in the subset had any chronic testing data available at all, and much of that was inadequate.[37] Chronic testing refers to the long-term animal testing needed to assess carcinogenicity of particular substances.

All this suggests that a slow pace of regulation is costly, not only in terms of ethical dilemmas and public trust, but also in lives lost. During the Carter years, OSHA was able to build a broad consensus on the need for a generic cancer policy by first addressing more minor issues. Hundreds of mostly irrelevant safety consensus standards were dropped from the books. Enforcement also became better focused. OSHA's reputation in the business and scientific communities improved considerably. Without these preliminary steps, it is unlikely the cancer policy and

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[36]"Occupational Diseases, 1977" Hearings before the Subcommittee on Labor of the Committee of Human Resources, US Senate, June 28, 29, 20, 1977, p. 1 and p. 53

[37]Toxicity Testing: Strategies to Determine Needs and Priorities, National Research Council, National Academy Press, Washington, DC, 1984

other broad initiatives (e.g., the right-to-know and employee access to medical records standards) would have ever seen the light of day.

How Reagan's OSHA Used "Regulatory Reform" to Prevent Implementation of the Cancer Policy

The official OSHA position today is that the cancer policy remains in effect.[38] Yet the agency no longer publishes lists of carcinogenic substances, and the courts have imposed additional requirements before the agency can adopt standards. Most notably, courts now require formal findings of significant risk, and additional economic analysis. Standards development for carcinogens continues to proceed slowly. Some argue that this is due to an unnecessarily strict interpretation by OSHA of various court rulings,[39] or by the reluctance of the Reagan Administration to regulate the business community. Reagan's view of regulatory reform meant a wholesale reduction in regulation, not the better focus championed by Carter's OSHA. Others have indicated that the agency's agenda is set by outsiders and the courts.[40] Still others, including members of Congress, have suggested that the limited staff resources of OSHA are a key factor.[41] Whatever the reason, most observers, including staffers at the National Institute for Occupational Safety and

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[38]Interview with anonymous national OSHA Staffer, February 1, 1988

[39]Dannon, B: "Perspectives on the Law and OSHA Standards Setting," Women's Occupational Health Resource Center News, September, 1987, p. 6-8

[40]Interview with Thorne Auchter, Ibid.

[41]"OSHA Head Questioned on Budget Needs, Agency Policies in Biting House Oversight," Occupational Health and Safety Reporter, Bureau of National Affairs, February 3, 1988, p. 1373. "'If I were you, to be very candid with you, I'd either scream or quit, and I don't understand why you're not screaming.' Rep. James M Jeffords (R-Vermont) told OSHA Head John A. Pendergrass....Jeffords contrasted Pendergrass' stated opposition to asking for more OSHA funding...with his statements that the agency struggles to hire and retain qualified inspectors because of low government starting salaries." This problem is even more acute at senior staff levels, where salary concerns combine with career concerns to produce a shortage of qualified professionals (see Chapter 2).

Health (NIOSH), which, in addition to other duties, serves as "research arm of OSHA," agree that in practice, the OSHA cancer policy is, for all practical purposes, ignored.[42] The policy is scheduled for an update in 1988, although the first deadline of January 1988 has already passed without action. John Pendergrass, the current administrator of OSHA, recently stated that the issue has "low priority."[43]

The Key Questions

This thesis will address the following questions:

1. Is a generic cancer policy needed?
2. Is the dominant model of a strict separation of risk management and risk assessment an accurate description of carcinogen rulemaking?
3. Is it possible to regulate entire families of chemicals more quickly without sacrificing due process and democratic norms? Or does scientific uncertainty doom us to a plodding substance-specific course of regulatory activity?
4. Are economic analysis of feasibility and quantitative assessment of socially acceptable risk levels compatible with our nation's democratic norms? That is, who decides what risks are acceptable?
5. Perhaps most importantly, how do generic and substance-specific rulemaking each affect employees at risk of exposure to carcinogens?

The answer to these questions will ultimately determine our success or failure in controlling, and ultimately eliminating, the workplace health hazards posed by a technologically-based society. The virtual elimination of infectious disease has added approximately 30 years to the average lifespan in this century, and perhaps more

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[42]Interview with anonymous NIOSH staffer

[43]Interview with John Pendergrass at the American Industrial Hygiene Conference, San Fransisco, California, May 16, 1988

importantly, improved the quality of life and expanded the opportunities for productive contributions. Elimination of cancer, if we can achieve it, will also revolutionize our nation's productivity and our quality of life. Due to higher exposures and relatively well-defined populations at risk, occupational hazards are often more easily detected than are environmental ones. The resources we choose to commit to this effort will in large part define the horizons for society's fight against cancer as a whole, even if it is true that occupational exposures account for only a small part of the total cancer incidence rate.

This thesis will begin by examining the history of the OSHA cancer policy, and how it followed other political developments both inside the agency and in society generally. The current state of the art of quantitative risk assessment, together with the utility of economic analytical tools (such as cost-benefit and cost-effectiveness analysis) are then reviewed briefly and contrasted with certain ethical dilemmas. A case study of methylene chloride is provided to assess how the 1980 version of the policy would have shaped regulation of this substance had it remained fully in place. Special attention is given to the use of pharmacokinetic data in the risk assessment of methylene chloride and in its ultimate classification. While some parts of the case study are speculative, it does show the potential value of the generic approach in reducing the number of lives lost to regulatory delay.

I conclude by posing the two alternatives we face under the constraints of scientific uncertainty, an ever-present feature of the cancer problem. If we demand firm proof before acting, industries may be less likely to suffer unnecessary regulation, but lives may be lost. If instead we adopt a prudent posture by acting on suggestive evidence, industry may suffer (and with it our rate of growth), but lives can be saved, and the moral dilemmas may be eased somewhat. In an era of abundant production, prudence may be more highly valued than continued growth.

A number of interviews with key players in the development of the policy have been completed for this study. These include four former OSHA Administrators, representatives of the National Toxicology Program, the National Institute for Occupational Safety and Health, the principal author of the 1980 policy, a high-ranking economist during the Carter Administration, representatives of industry and labor, a staffer from the Office of Management and Budget, and former President Jimmy Carter.

CHAPTER II

THE DEVELOPMENT OF THE OSHA CANCER POLICY

The Early Cancer Principles

The roots of the OSHA cancer policy lie in proceedings regarding pesticide regulation conducted by the Environmental Protection Agency (EPA) during the early 1970's. There is evidence of an earlier attempt to define cancer principles, brought about by disagreements among government scientists concerning addition of carcinogens to food. The Food Protection Committee of the National Research Council reported in 1970 that regulators could permit carcinogens to be added to food at "toxicologically insignificant levels," and further, that some substances could be considered safe without undergoing testing, based on past experience.[44]

Umberto Saffiotti, a scientist at the National Cancer Institute, responded by organizing a group of fellow scientists which eventually produced a report to the Surgeon General. The report indicated that a "safe level for man" cannot be defined by current scientific knowledge and that therefore no level of exposure to a chemical carcinogen is "toxicologically insignificant." It was suggested that a more realistic approach would involve a concept of "socially acceptable risk." Eventually, this concept formed the basis of the historic Supreme Court decision on benzene a decade later. Saffiotti's group also defined a number of other operational principles, including animal dose testing requirements, the supremacy of positive findings over negative findings, how to view benign and malignant tumors in animal

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[44]McGarity, TO: "OSHA's Generic Carcinogen Policy: Rule Making under Scientific and Legal Uncertainty, Law and Science in Collaboration, JD Nyhart and MM Carrow (eds), Lexington, MA, Lexington Books, 1983. Also see Office of Technology Assessment: Identifying and Regulating Carcinogens, US Congress, November 1987, p. 32-33

testing, prevention of synthetic carcinogen entry into the environment, extrapolation of animal testing results to humans, and a unified federal legislative approach to the problem.[45]

The Tension Between Scientists and Lawyers

Saffiotti later introduced these principles into EPA hearings on whether to cancel the registration for the pesticide DDT. The Report was also used by OSHA when it passed its "14 Carcinogens" rule in the early seventies. However, during hearings on the insecticides chlordane and heptachlor, and again during hearings on aldrin and dieldrin, industry and individual scientists indicated that the "substantive content" of the principles was wanting. In addition, EPA staff scientists reportedly felt that the scientific principles had in fact been drafted by lawyers, and were technically deficient. These concerns reached a crescendo during the hearings on the pesticide Mirex, when EPA lawyers attempted to have the principles adopted as "officially noticed facts." Saffiotti's principles, which had grown to 17, were subsequently reduced to three:

1. There is no scientific basis for defining a safe threshold for carcinogens,
2. Animal data can be used to assess risk to humans,
3. All tumorigens (substances capable of causing both benign and malignant tumors) be considered potential human cancer-causing agents.[46]

Anson Keller, one of the EPA lawyers involved in the DDT and other pesticide hearings, and others observed that many of the issues in each of these hearings had

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[45]US Department of Health and Human Services, National Cancer Institute, Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, "Evaluation of Environmental Carcinogens," Report to the Surgeon General, April 22, 1970, cited in OTA: Identifying and Regulating Carcinogens, Ibid. p.32

[46]OTA Ibid., p. 33

*been settled previously, but still had to be relitigated, and that this represented a substantial duplication of effort. Gradually, Keller took on more legal work at OSHA, and in fact was the only lawyer working directly with OSHA. Lawyers with the Department of Labor Solicitor General's Office had more indirect contacts with OSHA staff personnel.

The OSHA Administrator during the last part of the Ford Administration was an industrial hygiene scientist named Morton Corn, who had strong views about the need for more health standards. However, he felt that scientists should play the leading role in writing them, although Keller was put in charge of developing the carcinogen policy. Relying primarily on scientists meant more detailed, complete standards, but also further delays. This question of a slow time frame for standards development became public when an internal proposed calendar of regulatory actions was leaked to the New York Times.[47] Critics charged that the process was too slow to be effective.[48]

Nevertheless, most of the proposed carcinogen policy was completed under the Corn administration, drawing in large part on the work that had been done on the earlier coke oven emissions standard. Strong consensus had been developed between OSHA policy personnel and government scientists. However, due to the election year bureaucratic logjam, the policy was not proposed until early in the Carter administration, when it clearly carried the mark of Corn's successor, Eula Bingham, another scientist.

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[47]Burnham D: "Agency Assailed by Ford Defers New Safety Rules Till After Election," New York Times, March 4, 1976, p. 15

[48]Burnham, Ibid.

The Carter Administration: Activism at OSHA

OSHA As Ogre

Although Corn began the process of increased attention to health standard development, it was not until the Carter administration that the effort began to gather steam. To understand why, it is important to grasp the nation's consensus regarding OSHA at the beginning of the Carter Administration.

Former President Carter explained it this way:

> When I went to the White House I had had a long experience with OSHA as a businessman. I ran Carter's Warehouse, I had a peanut shelling plant, I ran a cotton gin...And my reaction to OSHA then was very negative. I didn't think they were rational. They were intrusive on occasion. A lot of times they would demand that we spend enormous sums of money with almost non-existent benefits to employees. OSHA was condemned roundly...Before I went into office, OSHA was looked upon as an ogre and one of the most despised federal agencies.[49]

The popular wisdom holds that the Jimmy Carter Presidency was plagued by an inability to act decisively. Instead of a chief executive leading a nation along a planned path, external events appeared to dictate policy decisions. The Iran hostage crisis, the energy crisis, inflation, welfare reform--all seemed to be beyond control. The President was widely perceived to be paying excessive attention to details.

> A president who would lead his administration, the Congress, and the country must...figure out what he wants and be able to communicate his vision and a sense of urgency to others...Above all, the president must be an effective political leader...and employ a strategic sense to gauge how much to propose and how much to settle for. Carter appears to have done few of these things....[50]

In short, he was accused of merely managing the government, not leading it.

However, the moves to reform OSHA during the Carter years seem to have been especially far-reaching. The agency adopted a labor-oriented activist posture

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[49]Personal interview with Jimmy Carter, November 12, 1987, Emory University, Atlanta, GA

[50]Lynn LE and Whitman DF: The President as Policymaker, Temple University Press, Philadelphia, p. 279-280

for the first time in its history. Many of the fundamental issues, such as how to deal with complex problems at the frontiers of science, how regulators can address uncertainties in modern science and technology, economic and political aspects of acceptable risk and the utility of cost-benefit analysis, and how to involve employees in plant health and safety matters, became the topics of formal rulemaking activities.

In spite of the President's apparent lack of direct involvement, the OSHA carcinogen policy (and the 250,000-page record generated to support it) carries his mark of attention to detail. Nearly all the objections and comments regarding the policy were answered by OSHA in a lengthy preamble covering nearly 300 single-spaced, small-typed pages in the Federal Register. To trace both the development of the rationale for the policy and how such a comprehensive policy became politically possible in an agency which, in earlier years, had been widely regarded as ineffective and a nuisance, it is necessary to examine the conflicts among the OSHA bureaucracy, other regulatory agencies, the President's Council of Economic Advisors (CEA), the White House domestic policy staff, industry, environmentalists, the scientific research community, and the labor movement. Internal documents recently opened for public inspection at the Jimmy Carter Presidential Library in Atlanta, Georgia are especially helpful in understanding these often complex relationships.

Efforts to Focus OSHA On More Serious Hazards

While it had its precursors,[51] the Occupational Health and Safety Act of 1970 was the first serious attempt to comprehensively enforce minimum standards in the nation's factories, mines, construction sites, and other workplaces. The previous system of state worker's compensation laws was widely perceived to be a failure,

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[51]See the Walsh-Healey Act, the Construction Safety Act, the Service Contract Act, and the Longshoreman's and Harbor Worker's Compensation Act

since they did not provide sufficient incentives for employers to maintain safe and healthful working conditions.[52]

When Congress enacted the law, it established timetables for development of those minimum standards. In order to meet the legislatively-mandated deadlines, consensus standards established by various professional groups and testing laboratories, such as the American National Standards Institute, the American Conference of Governmental Industrial Hygienists, the National Safety Council and various manufacturers of safety equipment, were included en masse, without regard to whether such standards were appropriate as enforceable laws by OSHA inspectors (compliance officers). The intent was to use such standards only until more permanent ones could be developed and recommended by NIOSH.[53]

Many of these standards were really recommendations that were not intended to become law. For example, inclusion of these standards meant that firms could be cited by OSHA if their fire extinguishers were not located exactly 38 inches above the floor. Toilet seats were required to be of a certain design, and dimensions of restroom facilities were specified. There were over 14 pages of detailed regulations on the construction of portable or temporary ladders, as well as specifications on sizes of knots, etc. Some of the earlier efforts were, if not sinister, certainly comical. At one point, OSHA issued a pamphlet on hazards in the barnyard, warning farmers of slippery conditions around livestock.

There is some question as to whether initial enforcement of these "nitpicking" laws was done on purpose to arouse opposition to OSHA. Speaking before a United

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[52]See "OSHA--A Four Letter Word," Washington Post, February 12, 1977, p 1A. Also see Berman, DM: Death on the Job: Occupational Health and Safety Struggles in the United States, Monthly Review Press, New York, 1978, for a history of worker's compensation laws

[53]Milius P: "OSHA--An Impossible Task," Washington Post, February 13, 1977, p. 1A

Automobile Workers Conference, Carter's Secretary of Labor Ray Marshall said, "We believe in these [OSHA] laws and we are going to try to make them work. There have been people in the past who did not believe in them and therefore did not try to make them work."[54]

The results of the "nitpicking" focus were predictable. By 1977, OSHA was perceived to be a failure by both businessmen and labor groups. A Washington Post reporter wrote, "To business groups and conservatives, it [OSHA] has become the leading symbol of what's wrong with the Federal regulatory process."[55] Ronald Reagan said, "OSHA is a 4-letter word that is giving businessmen fits and is helping drive up consumer costs."[56] Labor and environmental activists also denounced OSHA for failing to provide adequate protection for workers, especially against occupational diseases. They noted that in its first six years of existence, only four health standards were established to protect workers from exposure to the growing number of toxic chemicals used in industry. Sidney Wolfe, a spokesman for a Ralph Nader organization, said, "Nothing is going to happen until we have a well-informed group of victims."[57] This theme of providing information to workers is one that finds expression in later OSHA activities, and is a key element in the effort to develop a carcinogen policy.

OSHA also had its problems in Congress, as conservatives sponsored bills to "get the government out of the health and safety field" during the mid-seventies.

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[54]Dewars H: "Marshall Assures UAW of Action on Job Safety," Washington Post, March 3, 1977, p. C1

[55]Dewars, H, Ibid.

[56]Ibid.

[57]Op. Cit. "OSHA-- A Four Letter Word"

Examples include attempts to exempt over 90% of all businesses from OSHA inspections, use of independent inspectors, voluntary compliance schemes, etc.

As shown, there is evidence that Carter shared some of the complaints of businessmen regarding harassment by OSHA compliance officers. In a 1977 meeting with Charles Whitley, a member of Congress, the President said OSHA would more strongly enforce the health standards, and called OSHA safety inspectors "nitpicking."[58]

Carter attached great importance to the choice of who would head OSHA under his administration, finally settling on Eula Bingham, a biology professor from the University of Cincinnati.

> After impressing on [Bingham] his desire to stop OSHA's harassment of small businessmen and believing that she understood,...the President decided to name her...After lecturing Bingham, Carter conceded a need for OSHA.... But some businessmen don't seem to understand [the need for OSHA], and, he told Bingham, they include a peanut warehouse operator in Plains, Georgia named Billy Carter.[59]

The concession that there is indeed an important role for OSHA seems to suggest that the President knew that OSHA had to address truly serious hazards if it was to survive and perform its needed function. In short, his concern appears to have been for more than relieving businessmen of regulatory burdens. Bingham was far from a "safe" choice.

> ...Bingham scarcely seems the answer to a businessman's prayers. A crusader for more healthful conditions in factories, she has been called a health extremist. That is one description, Bingham has said privately, she is proud to accept.[60]

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[58]Carter Library, White House Central File, Box HE-7, File HE 4-2

[59]Evans R and Novak R: "Reassuring Businessmen," February 19, 1977, Washington Post, p. A13

[60]Ibid.

In fact, Bingham herself was surprised at the appointment, which had been suggested by officials of the United Automobile Workers (UAW). She provides the following account of her initial meeting with Carter:

> I was one of two subcabinet people interviewed by Jimmy Carter. I know that once Ray Marshall decided that I was his choice, (and I had not said I would take the job, and actually thought I wouldn't take the job), I got a call saying the President wanted to meet me, so Ray Marshall and I went over. He interviewed me and told me it was a very important job and asked me what I thought. I told him it was a very serious problem in the US and that I wasn't interested in some of the little things that didn't make any difference. You know, compliance officers dealing with whether a rail was 38 or 40 inches [high]. I was interested in health and safety features that made the difference between life and death and harm and so forth. Then he proceeded to tell me two stories. One story was about a facility in the Midwest, maybe Kansas, I don't recall, about how a company had made a place for people to eat outside on the patio, and they had a rail around the little fountain, you know it was one or two feet and the dropoff was minimal. The OSHA compliance officer came in and inspected the facility and had given them a citation because it was an inch off. Well it's a horrible story, really, when there's so much out there--that they would spend time doing that.
>
> Q: Was that a widespread problem?
> A: No I don't think it was a widespread problem, but once there was a story, everybody told it, and they wrote it up. I think the compliance officers were sometimes ruled by the attorneys, who read the letter of the law. I sent the word out very quickly that they should use judgement. One of the [compliance officers] told me that if you have to use a ruler, then you've got a problem. But if you look at it...experience [should tell] you what the appropriate height is to prevent you from falling to your death....
>
> Q: Some people say that in the early years...
> A: ...that it was done on purpose. I think there was some of that. But I think that... Mort Corn had been there for a year, [and he was] very good, and by the time I got there, there wasn't that much of that. But there was some.
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> The other story Jimmy Carter told me was that he was up in a plant in New Hampshire. This was a place where they did some work with asbestos. And he said, "I walked in there and started coughing and oh it was terrible and I said to one of the fellows, 'Boy!' And [one of them] said, 'Oh you think this is bad, you should have seen it before we cleaned it up.'" And Carter rolled his eyes at me, and we talked about how important the agency was...[61]

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[61]Interview with Eula Bingham, May 18, 1987

Within the first six months of his administration, Carter ordered the creation of an interagency task force chaired by Ray Marshall and Bert Lance to look at ways of strengthening the federal role in the regulation of health and safety in the nation's workplaces. On May 19, 1977, the Labor Department announced a program to "redirect the resources of OSHA away from trivial problems."[62]

Carter's Environmental Message of 1977: Linking Unimportant Safety Regulations with Slow Action on Health Problems

To what extent did Carter regard environmental protection and occupational health and safety as important national priorities? In a memo to the president, Stuart Eizenstat, his chief domestic policy advisor, noted that the absence of an environmental speech during the campaign was interpreted by many as a sign that Carter thought the issue was of low priority. The memo also noted that his appointments for the Environmental Protection Agency (EPA) and the Council on Environmental Quality (CEQ) had been late. Eizenstat concluded by stating that the President should establish environmental priority before addressing his energy policy.[63] The implication was that the energy policy was ultimately more important, but that it was important to allay fears from labor and environmentalists first.

In his environmental message to Congress on May 23, 1977, Carter said:

> In the past, implementation of the OSHA Act of 1970 has emphasized safety and too often resulted in unnecessary and burdensome regulations. Yet at the same time, federal response to health problems has been unconscionably slow.[64]

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[62]Memo to the President from Stu Eizenstat, August 5, 1977, Domestic Policy Staff Papers, Jimmy Carter Library, White House Central File, Subject File, Health 4-2, Box HE-7

[63]Memo to the President from Stu Eizenstat, Domestic Policy Staff, Jimmy Carter Library, Eizenstat Papers, Box 204, 3/30/77 CF, O/A 46

[64]The President's Papers, Carter, 1977, p. 970

This is the first linkage between safety and health standards, one that would eventually play an important role in creating the political conditions necessary for the development of OSHA's cancer policy.

The initial draft of the environmental message was written by the CEQ, and provoked a great deal of debate. A memo from Eizenstat to the President noted that the draft had "emotional language," which had been deleted. The draft in the Eizenstat file had the following phrases crossed out: "...the dark side of our industrial civilization...the environmentalists who warned us of this are resented by some people, perhaps because so many of their predictions have come true..." Some of the members of the CEQ, such as Gus Speth, a former lawyer for the Environmental Defense Fund who would eventually chair the Council, were regarded as environmental activists.

Another objection came from Charles Schultze, the President's economic advisor, who wrote:

> The opportunity is missed in this draft to move in new directions to harness the market in the fight against environmental degradation instead of continuing a system that rewards those that resist pollution curbs."[65]

This friction between the "economists" and the "environmental regulators" is a recurring theme throughout the Carter administration. In fact, Carter seems to have desired this interaction:

> I instructed both my director of OSHA and also the EPA people and the CEQ people to work together, strangely enough, with my Council of Economic Advisors...who were trusted by Wall Street and by manufacturers, to try to have some cost-benefit elements installed, and to see what OSHA could do to minimize paperwork and to maximize benefit to employees and employers, both in modification of existing plants and the design of newly constructed plants...In most cases they ironed out their differences between them.[66]

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[65]Memo from Charles Schultze to Stu Eizenstat, May 23, 1977, Eizenstat Papers, Box 204, File CF, O/A 29 [2]

[66]Interview with Jimmy Carter, Ibid.

Later in this chapter, we shall see that the relationship between the economists and the regulators was not as amiable as the former President suggests, especially with regard to cost-benefit analysis.

A memo to the President from a White House staffer on the Environmental Message stated: "If we are actually asking for an expansion of OSHA's efforts in the health area (where it has been wanting), we should put in some general language to show our sensitivity to the "over regulation" problem involving OSHA in the safety area."[67] This emphasis on regulatory reform was included in the message, which also called for a coordinated strategy against toxic chemicals. The message noted that there were more than 12 federal statutes implemented by 7 agencies, and that a more coordinated effort was needed. With the passage of the Toxic Substances Control Act, the message said, there was no need for further legislation, only better implementation.[68]

Who Should Coordinate?

With so many agencies involved, both economic and environmental, it became clear that some means of coordinating activity was essential. A meeting called by the Office of Management and Budget (OMB) in 1977 was apparently the first attempt at such coordination. The meeting was

> dominated by CEQ, which...interprets the President's Environmental Message to give it the lead...The reception of the participants [to this idea]...was friendly but skeptical, due to the large scope of the project...The four major toxic regulatory agencies--EPA, CPSC (Consumer Product Safety Commission), FDA (Food and Drug Administration), and OSHA have created a working group to coordinate their regulatory activities...My impression is this group appears...promising.

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[67]Memo to the President from Rick Hutcheson, May 10, 1977, Eizenstat Papers, Jimmy Carter Library, Box 204, File CF, O/A 29 [2]

[68]President's Environmental Fact Sheet, May 23, 1977, Eizenstat Papers, Box 203, Environmental Issues File CF, O/A 29 [1]

This memo from Si Lazarus to Stuart Eizenstat concludes by saying that this Interagency Regulatory Liaison Group (IRLG) is being kept relatively quiet, due to resistance from within their respective bureaucracies.[69]

It was the IRLG and later the Regulatory Council which played key roles in the development of a unified government carcinogen policy. While there were important differences between the carcinogen policies finally adopted by the EPA and OSHA, this type of cooperation among federal bureaucracies is noteworthy. It should serve to underscore the complexity of many environmental issues, which may not fit neatly into the legislative mandate of a single agency. Eula Bingham describes how the IRLG came into being:

> The first couple of months we [the administrators of EPA, FDA, CPSC, and OSHA] met each other and we decided that the things we had to do were similar. We decided we wouldn't reinvent the wheel and [that we would] get together and talk about what we were going to do. We would meet once a month, sometimes [more] often, in each other's office and cook breakfast for each other. We didn't have any staff people there, it was just the four of us (and then it got to be five when we brought in [a representative of the Meat Inspection Service from the Agriculture Department] and we would talk about what we were going to regulate, who in the White House was after us, or [who] from among the economists was causing a problem, what industries were giving us a problem. We used to call it circling the wagons.[70]

Such cooperation was reinforced by the perception of a common enemy, as indicated in the following account:

> In a hasty, last minute decision just before his October 24 anti-inflation speech, Carter agreed to appoint a new Regulatory Council, consisting of representatives of the executive branch regulatory agencies and excluding the Administration's inflation fighters. He thus resolved a bitter dispute between his top economic advisors...and his top appointees in...the EPA...OSHA...and FDA, who sought to exclude the inflation fighters...Schultze wanted to extend [the economists'] power to review, and possibly delay or alter costly agency

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[69]Memo from Si Lazarus to Stu Eizenstat Box 291, Jimmy Carter Library, Eizenstat Papers, Toxic Substances [O/A 6244] 6/29/77

[70]Interview with Eula Bingham, May 18, 1987

rules. But their plan provoked strong opposition from the agencies, which quickly developed the Council idea and convinced Carter of its merits.[71]

Thus, the "Big Four" regulatory agencies played the leading role in the development of the government's cancer policy. The CEQ apparently did not have the resources to conduct the detailed review of current scientific knowledge required, while the economists were seemingly unable to convince the President of their allegations about the adverse inflationary impact of new environmental health regulations, even though inflation concerns did play a much greater role later in the Carter Administration's term.

Unity on the question of a generic carcinogen policy was forged on two fronts. First, the IRLG was formed to attempt to unite the environmental agencies, with OSHA playing the leading role. Second, the Regulatory Council was formed to fend off the economists, and was led by Douglas Costle, administrator of the EPA. Anson Keller and others assembled a group of scientists from the National Cancer Institute (NCI), and, under orders from Eula Bingham, was instructed to strive for a consensus position from a wide range of government scientists as to what a proposed generic cancer policy would look like. Later, the effort was broadened to include non-government scientists.

Forging unity among the government scientists was not a simple matter. FDA had been preparing to make more extensive use of quantitative risk assessment, while OSHA was intent on holding to the position that its statute prevented such risk assessment. EPA wanted a non-regulatory approach (i.e. not legally-enforceable), which could change with the growth in scientific knowledge. This ultimately became the "guideline" approach currently used by the agency. Since it was the largest of the agencies, EPA also felt that it should play a leading role. At one

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[71] "What will Happen When the Regulators Regulate Themselves?" National Journal 11/4/78, p. 1769

point, it appeared that a unified position among the regulators would not be possible. A large, two-day meeting between members of the NCI and the IRLG finally resulted in a breakthrough, and a major paper was published in the Journal of the National Cancer Institute.[72] Eula Bingham is listed as IRLG Principal. Other members included Anson Keller, Umberto Saffiotti (of NCI), David Rall of the National Institute of Environmental Health Sciences, and representatives of FDA, EPA, CPSC, Office of Science and Technology, and the CEQ. This document formed the theoretical foundation for the OSHA cancer policy. One unresolved area concerned risk assessment, which EPA wanted to resolve by allowing public comment on the IRLG guidelines. OSHA's position was that this would prevent a policy from ever being finalized. EPA did conduct its own hearings on its version of the carcinogen policy, although OSHA did not testify at these proceedings.

On the other hand, the Regulatory Council appears to have been formed mainly to forge a workable unity among the regulators to prevent the economists from developing a stronger role in environmental regulatory affairs. Douglas Costle of the EPA appeared to play the leading role here.[73] Thus, EPA and OSHA appeared to develop a well-defined political division of labor.

Regulatory Reform and OSHA: The Accumulation of Political Capital

The reform effort at OSHA repeatedly received praise by the President and even some economists. In remarks before the Regulatory Council, Eizenstat claimed that no policy meant more to the President than regulatory reform. While this may be an overstatement (the President surely had major interests in the Middle East

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[72]Interagency Regulatory Liaison Group, "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks," Journal of the National Cancer Institute, Vol. 63, No. 1, July 1979, p. 241-268

[73]Interview with Eula Bingham, Ibid.

and Latin America, not to mention inflation and energy policy), it is fair to conclude that regulatory reform did receive substantial attention. Efforts by OSHA to reduce the number of needless regulations were repeatedly singled out for praise. However, there was apparently some lack of communication between the agency and the White House staff regarding the political use of the reform effort. Eizenstat told the President in a memo that "OSHA's bold initiative to discard 1100 'nitpicking' safety regulations...came as a surprise to the White House." He went on to state the need for some way to allow the Executive Office of the President to share credit for this action.[74]

On November 24, 1978, OSHA eliminated 928 minor safety regulations. Before this time, Bingham had made it clear that businesses were not to be cited on these unimportant standards. The Washington Post quoted Ray Marshall on May 20, 1977 as saying OSHA will no longer enforce "...petty regulations like those dealing with coat hooks in bathrooms." He went on to say the OSHA changes have "the strong backing of President Carter, who said he wants to "enforce the law rigidly," but with a maximum amount of support from labor and industry.[75] "Thus far, Bingham appears to be a Carter favorite....Carter [said] 'Few things the government has been doing domestically have gotten as favorable a public response as Eula Bingham's efforts to transform OSHA.'"[76] Anthony Mazzochi, a union official instrumental in

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[74]Memo to the President from Stu Eizenstat, September 2, 1978, Eizenstat Papers, Box 211, Government Reform File (1977) [CF, O/A 4]

[75] Dewars H: "OSHA will Quit Nitpicking, Go After Major Standards," Washington Post, May 20, 1977, p. A1

[76]Dewars H: "Rx for a Troubled Agency," Washington Post, September 12, 1977, p. A1

the passage of the OSHA Act said, "It's a sad commentary on our society when a person acts like the law intended, and my God, she becomes a celebrity."[77]

In an editorial, the Washington Post said, "OSHA seemed like a prime candidate for dismemberment...Bingham's moves, according to even OSHA's harshest critics, are all in the right direction...[If the reforms are unsuccessful]...getting the federal government out of the job safety field will have to be considered."[78]

Clearly, the move to delete unnecessary regulations created enormous political capital for OSHA, which was invested in future efforts to regulate cotton dust, lead, acrylonitrile, and other chemical exposures. In addition, it set the stage for proposing sweeping, more complex standards such as the carcinogen policy, the hazard communication standard (right-to-know), and the medical records access rule. The repercussions of both the administrative instruction from Bingham and the actual elimination of such a large number of regulations on the books gave teeth to Carter's regulatory reform effort.

Two influential groups approached this issue with differing and potentially conflicting objectives. The economic advisors were interested primarily in reducing the cost of regulation, while the regulators were attempting to make rules and standards more closely address the more serious problems of the day. This tension was understood by at least one White House staffer, and several regulators, as shown by internal White House memos:

> ...despite his urging that agencies think twice before making new rules, Carter is far from opposed to issuing complex and expensive regulations requiring a great deal of paperwork when he thinks they are necessary. (underlining

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[77]Dewars H, Ibid.

[78]Washington Post Editorial, September 17, 1977, p. A14

appears in Kitty Bernick's papers in the Carter Library. Ms. Bernick was a White House staffer).[79]

There was also some question concerning both the legality and political consequences of economic intervention in environmental regulations, a controversy that rages on today. Most of the agencies had been granted authority from Congress with specific mandates and duties. The role of the Executive Office of the President, Office of Management and Budget, and the Council of Economic Advisors in such matters has never been well-defined. The political consequences were also important. A memo to the President from Eizenstat and Lazarus stated:

> ...CEQ contends that Presidential or EOP review of regulatory decisions will offend environmental and labor constituencies. Others, including ourselves, believe that political damage would be even greater if it were perceived that the Administration had retreated from your earlier commitments to assure that regulations are cost-effective.[80]

The Economic Consequences of Regulation

Essentially, the economists argued that environmental regulations imposed a severe burden on the economy, and that the best way to solve environmental problems was through the use of market forces. There is a voluminous literature on this topic, dating back to the 1950's. In the Carter Administration, Charles Schultze promoted this idea most thoroughly in his book The Public Use of Private Interest. The advantage of using market forces, according to this line of reasoning, can be summarized as follows:

> Under an incentive-oriented approach, effluent charges, injury-rate taxes, or improved workman's compensation, the administering agency does not itself have to keep abreast of every new development. But if specific regulations

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[79]Malbin MJ: "Big Government or Small Government--The Candidates give Their Views," National Journal, January 26, 1980, p. 137 Reprint in Kitty Bernick Papers, Carter Library

[80]Memo for the President from Stu Eizenstat and Si Lazarus, October 18, 1978, Eizenstat Box 211, Government Regulations--Form [O/A 6243][1]

> are the only bar to prevent social damages, the regulatory agency must provide a regulation for every possible occasion and circumstance.[81]

However, such market-oriented approaches are less certain and may be even less timely than the "muddling through" regulatory approach. Costs often do not become evident until many years into the future, and there is an implicit assumption that the effects are reversible (i.e., that the environment is self-cleansing). In fact, some businesses may prefer specific regulations. "A charge for polluting, instead of the current regulatory morass, is less susceptible to manipulation...Business may be reticent to abandon this."[82]

There was considerable debate within the administration regarding the magnitude and nature of the costs imposed by environmental regulations. Juanita Kreps, Secretary of Commerce, cited a Brookings Institute study which said that environmental, safety and health regulations had retarded productivity growth by 20-25%.[83] Chase Econometrics predicted that environmental regulation would account for an average 0.3 to 0.4 points of the annual increase in consumer prices in the 1970-1983 period.[84]

In addition, the economists generally favored performance standards instead of specification standards. Since there may be more than one way of reducing or eliminating hazards, and if all those ways are equally effective, they argued that industry should be allowed to choose the most cost-effective method. The

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[81]Schultze C: The Public Use of Private Interest, Brookings Institution, Washington DC, 1976, p. 9

[82]National Journal 8/11/79, p. 1322

[83]Memo to the President from Juanita Kreps, May 26, 1978, Eizenstat Papers, Box 211, Government Regulations--Reform [O/A 62434][1], Jimmy Carter Presidential Library

[84]Cited in Green M: "The Faked Case Against Regulation," read into the Congressional Record of January 23, 1979 (House)

economists cited part of the OSHA Act, which says, "Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."[85] (emphasis added)

The Regulator's Rebuttal to the Economists

Essentially, the environmental regulators argued that the costs of controlling hazards, be they occupational exposure to toxic chemicals, safety hazards, or environmental contamination, are far less than the costs (financial and otherwise) of fatalities, health care, lost production, and lower quality of life suffered by those affected. They charged that these costs are often not borne by the individual firm, but are "externalized," i.e., passed on to society at large in the form of worker's compensation claims, health insurance, polluted environment, etc. By regulating a specific chemical, the costs are "internalized" for the individual firms. Thus, environmental regulations really impose no additional costs on society; in fact, they reduce costs, since regulations typically use preventive measures which are cheaper than medical and other after-the-fact treatments.

In the early 1970's, for example, the chemical manufacturing industry announced that the proposed OSHA standard on vinyl chloride, a known human carcinogen, could eliminate 2 million jobs and cost between $65 and $95 billion. However, after the standard was adopted, the industry flourished, with some individuals arguing that the health and safety regulations provided an incentive to make the manufacturing process more efficient by reducing the amount of vinyl chloride monomer left in the final polyvinyl chloride product (the monomer is the

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[85]OSHA Act, Public Law 91-596 Section 6(b)(5)

cancer-causing agent). No job losses have occurred and the cost for compliance has been about one-twentieth of the original estimate.[86]

The regulators also noted that in spite of general public complaints about excessive regulation, the Opinion Research Corporation conducted polls during the late seventies indicating that the public supported regulation to protect worker health and safety by a margin of 4 to 1, product safety by a margin of 3 to 1, and the environment by 2 to 1.[87] Some economists have suggested that such polls often do not phrase the question in terms of opportunity costs, and that if they did, support for such regulation might be considerably reduced.[88] Nevertheless, it seems clear that public support for this type of government activity is substantial.

The regulators also argued that increased regulation also tends to create jobs, not eliminate them. The EPA estimated that about 20,000 jobs had been lost in plants that could not meet various environmental standards, but that 600,000 jobs had been directly created by pollution control technology development and expenditures.[89]

This theme was echoed in Carter's 1977 Environmental Message to Congress, when he said, "...pollution controls generate more jobs than they have cost."[90]

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[86]Green, M, Ibid.

[87]Green M, Ibid.

[88]Rhoads, S: The Economists' View of the World, Cambridge University Press, New York, 1985, p. 27. For example, the question could be phrased, "Would you be willing to pay more taxes or repair fewer roads to pay for regulation to protect worker safety?" instead of, "Do you support worker safety?"

[89]Green, M, Ibid.

[90]The President's Public Papers, (Carter, 1977) p. 967

The Fight Inside the Administration

How did the President and his advisors line up on this question? The following account describes the sides involved and the impact of the anti-inflationary effort:

> The "fight" is a periodic one pitting the administration's regulators against such powers as chief economic advisor Charles Schultze, Treasury Secretary Michael Blumenthal, Commerce Secretary Juanita Kreps...and wage price watcher Barry Bosworth. The arena keeps shifting--from cotton dust standards to strip mining regulations, to carcinogen standards at OSHA--but the fundamental issue is the same: Should health and safety regulation be sacrificed to the anti-inflation campaign, based on the false specificity of existing cost-benefit analysis?...The choice is between the president as a cost-benefit econometrician or as a tribune for the victims of marketplace abuse."[91]

A letter from a number of Representatives complained to the President that his "...economic team is continuing to try to make...health regulations the Administration's scapegoat in the anti-inflation battle...Recent examples [include]...the OSHA carcinogen standard."[92]

This struggle essentially concerns the applicability of cost-benefit analysis to health and safety regulations. The philosophical and methodological issues are discussed in Chapter III. Here, the political struggle and OSHA's understanding of its obligations will be examined. The opening shot was fired when Carter decided to continue former President Gerald Ford's executive order requiring regulators to prepare an "Inflation Impact Statement" for any new proposed rules.[93] OSHA's position during the Carter years was that while it was necessary to analyze an industry's financial and technological capabilities to comply with a new rule (usually to determine time frames for compliance deadlines in various industries), its statute

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[91]Green M, Ibid.

[92]Letter to the President for House Representative Parren Mitchell, et al., February 12, 1979, White House Central File, Subject File Health 1-2 (Carcinogens) in Box HE-4, Jimmy Carter Library

[93]See Executive Order 12044

did not require the comparison of costs and benefits for the purposes of standard setting. Rather, its duty was to establish standards which protected employees and provided a workplace free of recognized health hazards, not whether the benefits of a particular proposal outweighed its costs. In both the asbestos and cotton dust cases, the courts ruled that an OSHA standard must assure, to the extent feasible, that no employee's health be impaired. In the asbestos case, an appeals court explicitly rejected the proposition that the law requires--or even permits--the Secretary of Labor to act on the basis of a cost-benefit comparison.[94] Bingham notes that:

> We fought and won, even with the Supreme Court, that we didn't have to do cost-benefit analysis according to that law [the OSHA statute]...But where metal came against metal was when we implemented standards that required a lot of retrofitting and new equipment. That's where the economists got heavily involved. The lead standard was literally held up. I didn't know it was really quite as bad as it was. I guess I should have been more frightened, but I [never was]. I knew it was the right thing to do.[95]

The lead standard is a very detailed health standard requiring extensive medical surveillance of exposed workers and a very low Permissible Exposure Limit, together with expensive engineering controls for specific industries.

Bingham spoke before a steel workers convention, urging them to lobby the White House to "free the lead standard." She also said that she and Ray Marshall would fight the "palace guard" around the President to get the standard issued and that economists are "complacent about cancer in the workplace." Finally, she

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[94]See the following court decisions: AFL-CIO v. Marshall, 617 F. 2d 636 (DC Circuit, October 10, 1979; American Textile Manufacturer's Institute v. Donovan, 452 US 490 (June 17, 1981);

[95]Interview with Eula Bingham

attacked the economists directly when she said, "To say that safety and health regulations are inflationary is phony."[96]

> In a memo complaining about these remarks, Eizenstat said, I do not believe it would be useful for anyone from over here to say anything to Eula about this, at this time,...but we are trying to show that the administration is working to reduce the costs of regulation in a responsible way--and on a unified basis. But if this sort of thing does not stop, what little chance we have to succeed will disappear.[97]

In fact, OSHA had no staff of its own to assess economic impacts, and had to hire outside consultants, a practice that continues today. Eula Bingham said, "OSHA spent $3.5 million preparing economic impact statements last year, three and a half times as much as what was programmed for the education of workers. Now that's an appalling thing!"[98]

Bingham's assessment of the relationship between economic and occupational health issues is instructive, especially since she claims that Carter was of like mind, once the technical issues had been explained to him (an issue that came to the fore during the struggle over the cotton dust standard). The Washington Post quoted her as follows:

> Workers have a right to expect they won't be killed on their jobs. If that means I have to pay 50 cents--or 2 dollars--more for my refrigerator, then I wouldn't want to hide it."[99]

In another interview, Bingham displayed a willingness to sacrifice marginal industries

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[96]"Steelworkers, Bingham Share Concerns Over Delay of Lead Standard Issuance, BNA Occupational Health and Safety Reporter, November 9, 1978

[97]Memo for Hamilton Jordan from Stu Eizenstat, December 6, 1978, Eizenstat Papers, Box 248, OSHA File [O/A 6465][1]

[98]Scott A: "Inflation Impact Statement Order Stirs Fierce Infighting, Washington Post, May 12, 1977, p. A5

[99]Dewars H: "Rx For a Troubled Agency," Washington Post, September 12, 1977, p. A1

which are unable to internalize their costs of employee safety and health, based on her concept of feasibility.

> Feasibility as defined in the OSHA Act and interpreted by the courts involves technical feasibility...and cost...You cannot put the whole industry out of business. But it is not unreasonable to kill off a couple of laggards...It was very hard to get numbers. If the technical feasibility was such that you could do it with no exposure, but you would put the whole industry out, then you couldn't do it. You would have to titer it back until you left the industry intact, but maybe one or two people fell by the wayside. They were probably having trouble surviving anyway.[100]

This is not radically different from Carter's stand in a message to Congress, when he said, "There are no economic tradeoffs to healthy water...Economic and environmental quality go hand in hand."[101]

Of course, economic and environmental quality can go hand in hand only if the cost of pollution or worker health and safety is borne by the firm, i.e., if the costs are internalized. If the costs have been shifted to society at large, this would indicate an inefficiency, since a greater amount of resources would have to be used. It costs more to treat workers for cancer than it does to prevent exposures to carcinogens in the workplace, if we look at social costs, not just costs to the individual firm. In other words, the most cost-effective way of controlling occupational disease and injury or environmental pollution is through an emphasis on prevention, not cure. Carter's commitment to cost-effective, necessary regulation seems clear in a briefing document:

> Question: Do you agree with Bob Strauss' comments about attacking environmental regulations because they are inflationary?
> Response: I am fully committed to the...Clean Air Act...and other environmental statutes. We intend to eliminate unnecessary regulations and to insure that other [necessary]

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[100]Interview with Eula Bingham, May, 1987, Ibid.

[101]See Carter's 1979 Message to Congress

> regulations are designed to achieve their goals in a cost-effective manner, as we have done with OSHA regulations."[102]

The emphasis on cost-effectiveness was perceived to be a way of avoiding the controversy surrounding cost-benefit analysis. In other words, once the goal has been determined, all that remains is to find the cheapest way of meeting that goal.

The White House staff's understanding of this issue is clarified in a memo from Kitty Bernick to Stu Eizenstat, which says in part:

> OSHA believes that its statute limits analysis to the technological and financial capacity of the industry and does not permit comparison or quantification of costs and benefits...as the basis for standard setting...Executive Order 12044 and the Administration's regulatory reform bill require the procedural step of analyzing costs and benefits, and, more important, considering less costly alternatives which would achieve the statutory objective. This approach does not require a rigid quantification and weighing of costs and benefits. Rather, it is a cost-effectiveness approach. By requiring the agency to identify alternative means of achieving its goals...the regulator is more likely to achieve the same results at less cost...Our point is that cost-benefit analysis is a useful tool, but it is not the only factor the decisionmaker can consider.[103]

Cotton Dust: OSHA's First and Last Victory Over the Economists

While the above explanation may sound like a neat compromise, what did it mean in practice?[104] The best example of the distinction may be the cotton dust regulation, which OSHA promulgated in June, 1978, under court order. Cotton dust exposure can cause byssinosis, also known as "brown lung," a particularly disabling lung disease suffered by textile workers. Bingham suggests that the President's domestic policy staff failed to serve him well in this instance, since they did not

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[102]Memo for the President From Stu Eizenstat, May 10, 1978, Briefing Document for Meeting with Environmentalists, Eizenstat Box 203, Environment General Issues [O/A 6240]

[103]Memo from Kitty Bernick to Stu Eizenstat, "Cost Benefit Analysis and OSHA," White House Central File, Box HE-7, File HE 4-2 1/1/79-1/20/81

[104]See Baram MS: "Cost-Benefit Analysis: An Inadequate Basis for Health, Safety and Environmental Decisionmaking," in Ecology Law Quarterly, Vol 8, 1980, p. 473-531 for an excellent discussion of the distinctions between cost-benefit analysis and cost-effectiveness analysis.

educate him regarding some of the specific issues involved. However, given his technical background, the President was able to learn quickly, and while he tended not to "meddle," he was "involved," when necessary, in occupational health and safety matters.[105]

Both the economists and Eizenstat held that respirators would be as effective as engineering controls in reducing exposures to cotton dust. This debate about engineering controls vs. personal protective equipment (such as respirators) continues today. An OSHA staffer indicated that one of the key provisions, the "teeth" of the OSHA cancer policy, concerns the preference for engineering controls over respirators.[106] In this respect at least, the OSHA cancer policy remains in effect today.[107] For example, the recent OSHA formaldehyde standard calls for engineering controls to be used as the primary means of reducing hazards; respirators are to be used only as a last resort. However, in practice, OSHA rarely enforces engineering control provisions of standards.

Respirators are devices worn by workers that may filter out some fraction of the cotton dust in the workplace air, if used properly. Engineering controls typically include such techniques as ventilation, process changes, and enclosures designed to prevent cotton dust from entering the workplace air at all. It is a basic principle in the practice of industrial hygiene that engineering controls should constitute the first line of defense, and that respirators can only be used when engineering controls are not technically feasible, or until engineering controls can be installed. Calling for use of respirators in place of feasible engineering

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[105]Interview with Eula Bingham, Ibid.

[106]Interview with anonymous national OSHA Staffer, February 1, 1988

[107]This is true for standards-setting programs only. In enforcement, engineering standards are rarely enforced.

controls is like asking a doctor to prescribe a sulfa drug instead of a modern antibiotic, simply because it is cheaper. Of course, no one would consider imposing such a requirement, since the sulfa drugs are known to be less effective. Similarly, it is well-known that, in the real world, respirators are in practice less effective than well-designed engineering controls.[108]

Yet this is precisely what the President's economic advisors and his chief domestic policy advisor wanted. A recent book on economics persists in labelling this question as one of examining alternative costs among equally effective means of controlling worker's exposures.[109] Eula Bingham's review of the events leading up to the promulgation of the cotton dust standard is noteworthy in that it clarifies where Carter himself stood on these issues, and how his staff insulated him from the issues involved. Her account follows:

> [The White House staff] knew the economic issues, but they didn't know the scientific issues, the biology of it or the toxicology or the medical aspects. Of course, if they had, they'd have been on our side. Once the confrontation happened, and we won very big with Carter, my influence loomed very large and theirs was not as great. It was crazy and ...strange how it happened. They were more intimidated by Ray Marshall and myself because I guess they thought Carter agreed with us or liked us or something.
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> It was early enough so that we had some room, in spite of the anti-regulatory moves in Congress and among the economists.
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> OSHA had been sued by the unions and the brown lung association [a victims' interest group] about the cotton dust standard, and we were under a court order to have it out by the first of May, I think. By the first of May we had it all done, except it still had to go through some of the regulatory review.

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[108]"When it is not feasible to render the working environment completely safe, it may be necessary to exclude the worker from that environment by the use of personal protective equipment (this is normally considered to be secondary to engineering and administrative controls)...Personal protective devices have one serious drawback--they do nothing to reduce or eliminate the hazard. The supervisor must be constantly alert to make sure that required respiratory equipment is worn by those workers..." from Olishifski JB: Fundamentals of Industrial Hygiene (second edition), National Safety Council, 1979, p.38

[109]Rhoads, Steven E: The Economist's View of the World, Cambridge University Press, 1985, p. 18

We had decided to go with a standard that said the industry had a year to assess the problem and decide what they needed and that they had to put the controls in place as soon as possible, but not longer than seven years. They had to put in engineering controls and could not rely on respirators.
Charlie Schultze was against it. He wanted everyone to have the same amount of time and to use respirators and no engineering controls. Eizenstat or someone prepared the briefing memo, and this was Charlie's big stand. The plaintiffs gave us until the end of May. So we were within a day of that, and Charlie Schultze called Ray Marshall up and said (and the word had already gone out on the street to the press) that Charlie was going to have a press conference at 9 o'clock, and he was announcing the new cotton dust standard. Well, you know, you can't do that, it's against the law.... He was announcing a cotton dust standard that was going to be essentially respirators, and everybody had the same length of time, seven years. We had said as soon as possible, but no longer than seven years, and engineering controls. They had made this briefing memo and the President had gone along with it. Ray Marshall got him on the phone and just read the riot act. He never cursed, but he said, "Damn it Charlie, don't have that press conference because I'm going to talk to the President."

So he got through to the President, he said it's an emergency, I've got to talk with him. I was in the room and the President said to him, "Well, if the facts are like you say, those issues were never presented to me." And Ray said, "Well, I don't think your staff has served you very well, because this is the way it is." [The President] said, "We'll have to get together and talk about it, but I don't know, I've already given Charlie the go-ahead." Ray said, "I'll take care of Charlie," and the President says, we'll get you on the calendar this afternoon. So Ray got on the phone and told Charlie to absolutely not have the press conference, that there was no standard, and nobody was going to sign it, and hold up on everything. We were worried he would go out front, and then it would be very hard to call it back. So he didn't have it.

Once [Marshall] got the appointment with the President, he said, well, figure out what you're going to say to the President to convince him. The first thing I did was call in my staff, my political appointees that had come with me, and we all cried. I said I don't think there's a chinaman's chance of changing the President's mind. But Ray told me we had to try. I recall Chuck Knapp, who is now going to be the President of University of Georgia, saying, "well I wouldn't give you much hope." I said I don't know whether I'll leave tomorrow or the first of July, but I won't stay, if he goes forward with that. I said I just can't stay, professionally. I called Irv Selikoff and called John Peters and several other people and told them, this is what I'm faced with, what would you do if you were me? And they said you can't professionally stand for putting respirators on people as the first line of defense and I said well, that's the way I feel about it, [too]. I got classical references where the hierarchy of controls are named very briefly, where it's very clear what the field of occupational medicine and industrial hygiene have considered to be the way you deal with these things over the years...that you use respirators as a last resort.

> We got to the President's office and there was Stu Eizenstat, Charlie Schultze, the President, Ray Marshall, myself, and Fritz Mondale. Fritz Mondale came to help us out. Nobody else was there. The President said, "Well, tell me your side of the story," to Ray. Then Ray said a little bit, then they asked me to tell my side. Then Charlie proceeded to tell what he thought the standard should be, and Stu talked also. Charlie explained this stuff about the free market, and that you had to let everybody have the same amount of time, otherwise it was not fair. So the President sat and listened, and then he said, "Well, how does this sound, Eula? I think we ought to give them 18 months to do their survey and then everyone ought to have everything in place at the same time in five [instead of seven] years. And they should wear respirators until they can get everything in place, all the engineering controls, wouldn't you agree? How does that sound Eula?"
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> I looked at Ray Marshall and he looked at me and I almost sobbed, and I thought, Oh I didn't hear him right. So I said, "Could you please repeat that?" So he repeated it and Charlie was sitting over there, just getting angrier and Stu was just furious. Mondale was smiling, and I thought, well, he couldn't have known this all along. I said, "Well it sounds good to me."And he said, "Well, it's settled." And Eizenstat says, "What do you mean it's settled? I think you ought to sleep on this." The President says, "Well, there's a court order on this, you don't want Ray or Eula to go to jail." [Eizenstat] said, "Well, I don't think we should do this now, you can't make that decision now." And [the President] turned to him and said, "What do you mean I can't make that decision now? I'm the President."
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> You know what they wanted to do, they wanted to have another chance at him. He said, well, it's settled. He said to Charlie and Stu, "You meet with them and work out any of the details." Everyone left except the President, Ray Marshall and myself, and [the President] engaged us in a conversation about the Willow Island thing [where many workers died as a result of a tower collapse due to "green concrete."]. It was a gracious signal that said that he agreed with us. That was my reason for the "palace guard" comment [I made earlier]. I knew they [Schultze and Eizenstat] were kidding themselves. The President wasn't going to stop a lead standard!"[110]

The President's Personal Experience as a Farmer

The President's decision on cotton dust may have also been a result of his own personal experience in Plains, Georgia:

> I ran a peanut shelling plant...The job is to clean the dirt from the peanuts. In dry weather, clouds of impenetrable dust cover the people who are running the plant, including me and my brother and my employees...If you're growing seed peanuts, which is my main business, then you treat them with chemicals to prevent rot in the ground...that are poisonous. We used...a mercury-based treatment at that time, and all the labels say wear a respirator. I never could

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[110]Interview with Eula Bingham, May, 1987, Ibid.

> get an employee to wear a respirator for more than an hour or two...They just wouldn't do it. And I never wore a respirator. I knew that I ought to, but you look kind of stupid running around trying to buy peanuts from a bunch of farmers with a white gauze mask on your face or something else...I knew there was no way you were going to make all the employees in a cotton mill wear respirators, even if you offered them and gave them respirators...My experience [in these environmental matters] is limited, but in this case it was not. A lot of the cotton mills I had visited while I was campaigning had cotton fibers floating in the air.[111]

Clearly, the experiences of a decisionmaker matter as much as the advice he or she receives.

The Effect on the Business Community

That cotton dust was a setback for Schultze can be seen in his memo to the President of September 29, 1978, where he says,

> Cotton dust was seen as a "defeat" for [the Regulatory Analysis Review Program] and its advocates. The outcome confused participants in the Executive Office of the President and regulatory agencies about the degree of Presidential support for the Regulatory Analysis Program. The failure to identify costs of regulations is a tactical error. It feeds the business community...which wants to do away with environmental regulations.[112]

There may be some truth to this. The failure to make a formal finding of significant risk or conduct some form of cost-benefit or cost-effectiveness analysis in the benzene case is now widely viewed as a tactical mistake. For example, Anson Keller and others now believe that the agency should have argued that even though the OSHA act does not require it, a risk assessment and rudimentary economic analysis must be completed to deflect opposition.[113] OSHA now routinely performs risk assessments for all new standards.

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[111]Interview With Jimmy Carter, Ibid.

[112]Memo from Charles Schultz to the President, September 29, 1978, Eizenstat Papers, Box 211, Government Regulations--Reform [O/A 6243][1]

[113]Interview with Anson Keller, Ibid.

The fact that the Secretary of Labor, Ray Marshall, was also an economist may have played some role in countering the White House advisors' emphasis on costs to industry. In fact, Charles Schultze is quoted as saying that "the President is very impressed with Ray Marshall."[114] Another summation of Marshall also sheds some light on his relationship with the President: "He [Marshall] is very much in the mold of Carter: cool, self-confident, impatient with ideological musings that don't produce results."[115]

Joseph Califano, Carter's Secretary of Health, Education, and Welfare, also weighed in against the narrow economic view: "It is myopic to argue that programs to protect workers are inflationary, if we do not count what these programs buy."[116]

"Counting what these programs buy" is precisely what makes a quantitative economic analysis of health standards problematic at best. For a single substance, where some reasonable estimates of workers exposed is available, where toxicological mechanisms are well understood, and where the economic benefits can be roughly approximated, calculating the benefits of a particular standard or regulation may not be completely beyond the realm of the imagination. However, when families of chemicals are regulated, and when the state of knowledge is in its infancy, as it is with carcinogenesis, then quantification may well be impossible.

The question of the utility of economic analysis will be examined in greater detail in the following chapter. Historically, however, it should be clear that the beginning of the ascent of economists in environmental matters began during the Carter years. The cotton dust case was merely a temporary setback. The anti-

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[114]Dewars H: "The New Labor Secretary: Not Exactly an Outsider," Washington Post, February 20, 1977, p. F1

[115]Dewars Ibid.

[116]Richards B: "Study Sees 20% of Cancer Cases as Work-Related," Washington Post, September 12, 1978, p. A1

regulatory bent of the Reagan Administration, combined with the Supreme Court decision on benzene, has effectively ensured the supremacy of economic and risk analysis during the eighties.

The Public Debate: What Causes Cancer?

The cancer issue was put squarely before the public in the late seventies. By then, it had become clear that regulating chemicals on a one-by-one basis would fail to meet the requirements of the OSHA Act. In 1978, the American Chemical Society estimated that 4 million chemicals were in existence, with about 6,000 new ones being identified each week. About 44,000 of these were thought to be in common use in the US.[117] Some fraction of these chemicals are carcinogenic, and there was a vigorous national debate over whether these substances were responsible for a "cancer epidemic."

In hearings before the Senate in 1977, it was reported that 21,000 chemicals in common use were known to be toxic, and that of these, 2,400 were suspected of causing cancer. At the time, OSHA regulated only 16 of the 2,400 as carcinogens (14 in the early carcinogens rule). About 300,000 workers were exposed to these 16 alone. Nationally, it was reported that there were more than 100,000 deaths from occupational diseases (not all cancer), and another 390,000 new cases of occupational disease annually. This can be compared to the approximately 14,000 annual deaths that were due to industrial accidents.[118]

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[117]Chemical Abstracts Services: "Registry Passes 4-Million Mark; Uses Grow," CAS Report, 1978: 7:2, cited in Calkins DR, et al.: "Identification, Characterization and Control of Potential Human Carcinogens: A Framework for Federal Decisionmaking," Journal of the National Cancer Institute, Vol. 64, No. 1, January, 1980, p. 169

[118]"Occupational Diseases, 1977," Hearings before the Subcommittee on Labor of the Committee of Human Resources, US Senate, 91st Congress, June 28,29, 30, 1977 p. 1 and p. 53

Estimates of the percentage of cancer caused by environmental factors varied widely. In 1977, the National Cancer Institute said that about 90% of all cancers were environmental in origin,[119] implying that, theoretically, at least, they were preventable. A report by the National Cancer Program estimated that 40% of all cancers were due to smoking, 10% were due to chemical carcinogens (of which half could be considered to be occupational cancers), while the causes of the remaining 50% were still unknown.[120] In 1978, The Department of Health, Education, and Welfare (HEW) reported that 20-40% of all cancers were attributable to occupational factors (not just "environmental" factors). Industry typically reported the figure at 1-5%.[121]

In fact, the HEW study was done in response to an earlier study. Since industry's claim that only a very few cancers were occupational in origin, this would probably not constitute a "significant" risk. OSHA realized that it would not be able to regulate occupational carcinogens generically, unless it could be demonstrated scientifically that a greater percentage of cancers were due to occupation. A paper published in the National Cancer Institute journal looked at asbestos exposures and decided that this substance alone accounted for 10 % of all cancers. Total occupational factors causing cancers were pegged at 20-40%.[122] Although there was never any consensus on this in the scientific community, the

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[119]Greenberg, DS and Randall, JE: "Waging the War on Cancer: How the American Cancer Society Focuses on the Search for Cures Rather than Environmental Causes," Washington Post, May 1, 1977, p. C1

[120]White House Central File, Box HE-4, File HE 1-2 4/18/79-1/20/81

[121]Bernick Papers, Box 10, OSHA Carcinogens [3]

[122]Bridbord, K, et al.: "Estimates of the Fraction of Cancer in the US Related to Occupational Factors, National Cancer Institute, National Institutes of Environmental Health Sciences, National Institute for Occupational Safety and Health, Bethesda, MD, 1978

HEW study blunted industry's contention significantly, and allowed the rulemaking activity to continue.

On NBC's Meet the Press" of June 25, 1978 the issue also received media attention:

> Q: Dr. Selikoff [Director of the Environmental Sciences Laboratory, Mount Sinai School of Medicine], according to reports, cancer has become the primary health concern of the American people, and the fear of cancer has taken on epidemic proportions. How justified do you consider this fear? Is there an epidemic?
> A: Well, if you consider that twenty percent of all Americans now living are going to die of cancer unless we do something about it, I think that is a fairly justified fear.
> Q: Dr. Upton [Director of the National Cancer Institute], do you consider that an epidemic?
> A: I don't think the incidence is epidemic in the usual sense, although it is common...If we look at the overall incidence, there is some drift upward which cannot be attributed to cigarettes, but I wouldn't say it has become epidemic.[123]

In some ways, arguments over the exact percentage of cancers attributable to a specific cause miss the point, since many cancers are preventable, and are likely to have multiple causes. The generic carcinogen policy was only part of an effort by OSHA to bring this complex issue before the public. In 1979, OSHA sponsored a conference with the title: "Lost in the Workplace: Is There an Occupational Disease Epidemic?" The conference brochure described a "massive yet silent slaughter," language which prompted a sharp response by the American Industrial Health Council (AIHC). Its president wrote a letter to Ray Marshall, stating that:

> The AIHC wishes to express its grave concern over the language which the Department of Labor has used in describing this seminar...Its use of [such] language...is offensive in tone...We challenge the suggestion that there is an epidemic in the workplace and we specifically challenge the 100,000 annual death rate [figure]. We ask that you [Ray Marshall] publicly disassociate yourself and your department from such unfortunate rhetoric.[124]

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[123]"The Environment: How Cancerous?" NBC's Meet the Press, June 25, 1978, published in Annals New York Academy of Sciences, 1978, p. 799

[124]Letter to F. Ray Marshall from W. C. Krumrei, American Industrial Health Council, September 4, 1979, Kitty Bernick Papers, Box 10, OSHA Carcinogens [2]

Why did OSHA choose to use such explicit language? Part of the reason may lie in the fact that the agency was seeking a fundamental change in the way we perceive chemicals in general. In her response to the letter, Bingham wrote:

> "Faced as we are with a constantly expanding body of scientific and medical knowledge that today finds chemicals to be hazardous that were earlier believed to be harmless, we have no reasonable alternatives but to view all chemical exposures as potentially hazardous."[125]

In short, OSHA was attempting to use knowledge that had previously not been used, i.e., to shift the burden of proof. This is also an issue that came to the fore during the "Meet the Press" interview cited earlier:

> Q: Dr. Selikoff, you pioneered in research that has identified asbestos as a potent cause of lung cancer. The health hazard of this substance has been known for at least fifty years. Why does this substance remain in large use in the American economy?
>
> A: (Selikoff) In considerable part because we haven't used the information that we have...
>
> A: (Dr. Kotin - Vice President of Johns-Manville Corporation, a leading asbestos manufacturer): ...a significant portion of the chemicals in the workplace that have been identified [as hazardous] were identified by industry-supported research in advance of the pressures by OSHA.
>
> A: (Mr. Mazzochi, Vice President, Oil, Chemical and Atomic Workers Union): Dr. Kotin's statement about what industry has done is pure nonsense. American industry has not divulged one single item about a cancer-causing substance to workers...I think the industry has the best of all worlds. Work is with guinea pigs. All we know about cancer is based upon what happens to workers. We don't use animal studies; the industry opposes that approach; and certainly the work they have done they refuse to divulge. Remember, industry to this date refuses to tell us what we work with, is it cancerous, how much of it is present...You absolutely walk into the most cancerous workplaces in America blindfolded, as workers.[126]

Bingham argued that there were essentially two choices: "Wait for a body count of dead or seriously ill workers, as we did with Kepone, beta-naphthylamine, benzidine, and coke oven emissions, or we can rely upon animal testing [and] other tests."[127]

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[125]Remarks by Eula Bingham on the OSHA Carcinogen Policy, Bernick Papers, Box 10, OSHA Carcinogens [3]

[126]NBC's Meet the Press, Ibid.

[127]Bernick Papers, Bingham Remarks, Carter Library, Ibid.

The AIHC, with a membership of 120 companies and 60 trade organizations, was apparently formed in response to the OSHA proposed carcinogen policy. It was established in October, 1977 (the same month OSHA published its proposed carcinogen policy), to "assist the US OSHA in developing rational and practical policies for regulating potential carcinogens in the workplace."[128] AIHC's "Report to the Membership, 1987" explains how the AIHC was founded:

> Because of this policy's far-reaching implications--legal, regulatory, scientific, and economic--a group of senior corporate executives from several industrial sectors saw the need to create a new group to address the issues raised by OSHA's cancer policy. These executives and their association colleagues established the AIHC.[129]

However, there was no discernible organizing strategy by labor, which seemed to confine itself to issuing public statements supporting the policy.[130] Perhaps this was due to labor's belief that OSHA would accurately present their views. Another possibility is that labor has traditionally been more concerned with enforcement, rather than standards-setting. Finally, organized labor has not retained scientific expertise in these complex areas (see Chapter V).

The proposed cancer standard[131] became the subject of extensive hearings, and by the time the final policy was published in January 1980,[132] the AIHC had spent over $1.3 million in legal fees and had hired an accounting firm to perform a cost-benefit

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[128]Handwritten notes in Bernick papers, author unknown, Box 10, OSHA Carcinogens [3]

[129]"AIHC Report to the Membership, 1987 1977-1987: A Decade of Change," Washington DC, p. 3

[130]Russell, Cristine: "Controversial OSHA Cancer Hearing Opens," Washington Star, May 17, 1978, p. 3

[131]42 FR 54148, October 4, 1977

[132]45 FR 5002, January 22, 1980

analysis.[133] The latter was an especially difficult proposition, since the policy did not even name specific chemicals to be regulated.

The AIHC appears to have been "well-connected" at the White House. While the OSHA position and the AIHC positions on carcinogens were diametrically opposed on many issues, the rulemaking record is a model of public participation, with due consideration of widely varying viewpoints on nearly every conceivable facet of the proposed regulation. But, the AIHC complained to White House staffers regarding their "poor" relationship with OSHA, and apparently successfully won over the President's advisors on some points. One staffer wrote that OSHA's proposal was not "sensible," calling it a modified Delaney clause,[134] since it would essentially eliminate any workplace exposures to known human carcinogens. (The Delaney Amendment was passed by Congress, requiring the FDA to prohibit the addition of any carcinogen to the nation's food supply.) The comparison with the Delaney clause was a key part of industry's objection to the OSHA carcinogen standard, since industry charged that OSHA was seeking a "zero-risk" workplace that was impractical and not achievable. Another memo from White House Staffers Si Lazarus and Kitty Bernick indicated that they were "monitoring" OSHA's work and that "although the regulators generally object to AIHC, Katie and I have found them fairly easy to work with."[135] Another White House memo stated that, "the AIHC has been quite helpful and supportive on the Regulatory Reform Bill."[136]

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[133]Firms, OSHA Wrangle Over Carcinogen Rules," Washington Post, July 1, 1978, p. A6

[134]Memo from Si Lazarus to Stu Eizenstat, August 11, 1979, White House Central File, Box HE 4-2, 1/20/77-1/20/81

[135]Memo from Peter Petkas to Si Lazarus re meeting with AIHC, Nov. 5, 1979, White House Central File (Commodities) Box CM-1

[136]Memo for Kathy Reid from Si Lazarus, October 23, 1979, Bernick Papers, Box 1, AIHC Folder

The initial OSHA proposal was roundly condemned as being inflexible and not having a defensible prioritization scheme for which carcinogens to regulate first. The preamble to the proposal recognized that initially there would be a tremendous backlog of carcinogens to be regulated and classified. One of the options presented was particularly ridiculed: Proceed alphabetically through a list developed by NIOSH.[137] Anson Keller has stated that this was merely one of many proposals that was put in at the eleventh hour without thorough examination.[138]

Although the alphabetical approach certainly is wanting, it is nevertheless interesting to note that a disproportionate number of regulated substances begin with letters at the beginning of the alphabet. Consider the list of chemicals specifically regulated by OSHA in a health standard:

arsenic
asbestos
alpha-naphthylamine
4-aminodiphenyl
acrylonitrile
bis-chloromethyl ether
benzidine
benzene
coke oven emissions
cotton dust
coal tar pitch volatiles
ethylene imine
ethylene oxide
formaldehyde
methyl chloromethyl ether
lead
vinyl chloride

It seems likely that any relationship between the substance's first letter and its regulatory fate is spurious. Nevertheless, it does underscore the potential dangers in the haphazard substance-specific regulatory technique.

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[137]42 FR 54169

[138]Keller Interview, Ibid.

The Public Debate: How OSHA Addressed Scientific Uncertainty

As we have seen, the OSHA cancer policy was part of a broader government effort to establish broad guidelines on how cancer-causing substances should be controlled. The IRLG (consisting of the EPA, OSHA, FDA, and CPSC), together with the Office of Science and Technology Policy (OSTP) all worked to develop a unified policy that, while not immediately naming specific substances, would aid in classifying suspected substances. It is worthwhile to summarize the Preamble to the OSHA 1980 cancer policy at this point. The classification scheme was intended to be used to determine the degree of control necessary. In other words, the new policy was expected to shorten rulemaking dramatically, and avoid "reinventing the wheel" for each new substance.

Specifically, the preamble cited the experience of the vinyl chloride regulation. Vinyl chloride was, at the time of its regulatory hearings, undisputably a human carcinogen. Yet there was extensive controversy over whether a "safe" level of exposure was possible, whether animal testing data using high doses could be extrapolated to humans exposed to lower doses, the appropriateness of specific requirements, etc. In spite of the 600 written comments, 200 written and oral submissions, numerous hearings, and a 4,000 page record, OSHA concluded that definitive answers to such questions had not been provided. But "...we cannot wait until indisputable answers to these questions are available because lives...are at stake."[139] Other substances had also taken considerable time to regulate:

Asbestos	29 months
14 carcinogens	40 months
Coke oven emissions	greater than 66 months
Arsenic	greater than 67 months
Benzene	greater than 31 months

[139]39 FR 35892, October 4, 1974

Beryllium	greater than 51 months[140]

Thus, the policy's intent was to limit unnecessary, repetitive debate in the future.

> It is necessary to strike a balance between some limitation of scientific discussion, which is necessary to avoid regulatory paralysis, and the flexibility to consider exceptional cases and to accommodate new scientific advances.[141]

This statement shows how risk management decisions can drive risk assessment analysis. With the policy in place, the only points of contention would be how a particular substance had been classified, and whether the animal studies, or other tests, were of sufficient quality, which is the heart of what we now call risk assessment.

The Need to Act

During the testimony, officials from the National Cancer Institute reported that cancer rates had been increasing during the seventies at a 2% per annum rate, with about 25% of the people in the US expected to develop some form of cancer (excluding skin cancer) during their lifetime.[142] Yet the pattern of incidence is remarkably complex, and appears to include more than single factors, i.e. cancer usually progresses through a number of stages of development, with different factors acting at each stage. The Director of the National Institutes of Environmental Health Sciences testified that,

> It makes little sense to assert that "only" 1-5% of cancers are attributable to a single factor...All cancers are associated in one way or another with

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[140] 45 FR 5012, January 22, 1980

[141] 45 FR 5014

[142] 45 FR 5015-5016

occupational factors, just as they are probably all associated with dietary factors, genetic factors, and hormonal factors."[143]

Traditional toxicology was also described as being inadequate in dealing with carcinogens, because the effects of most other poisons are usually reversible, are comparatively rapid, and exhibit a dose-response function. None of these are true of carcinogens. When dealing with acutely toxic substances, early toxicological studies could "find a no-effect level in animals, divide by 100, and pray."[144] However, tumors typically take anywhere from 5 - 40 years before becoming manifest. Many cancers appear to be caused by changes in a single cell, suggesting that the changes are not reversible, unlike most other toxic substances. Finally, no truly "safe" level of exposure has ever been demonstrated for any carcinogenic substance. Rather, a probability function relating the likelihood of cancer with the dose received is often described. However, there does not appear to be any dose at which cancer is not possible. The preamble stated that the long latency period makes it impossible to wait for the results of human epidemiological studies to estimate this probability function.[145]

The AIHC argued that if given sufficiently high doses of any substance, animals are likely to become seriously ill and more susceptible to cancer.[146] In other words, the AIHC held that all substances were likely to be carcinogenic. However, OSHA cited other experts who testified that in fact only a relatively few

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[143]Testimony of Dr. David Rall, Director National Institute of Environmental Health Sciences, 45 FR 5020

[144]An anonymous British toxicologist, quoted by Umberto Saffiotti, 45 FR 5023

[145]45 FR 5023

[146]45 FR 5028

chemical substances have been found to produce cancer, even at relatively high doses.[147]

The National Cancer Institute, National Institute of Environmental Health Sciences, and the National Institute for Occupational Safety and Health all released reports stating that a substantial fraction of cancers in the US is occupationally related, and that this is not inconsistent with saying that they are also related to other factors as well. The AIHC argued that this involved "double or triple counting." OSHA replied that "AIHC's criticism...is not consistent with the scientific consensus on the multi-causal nature of carcinogenesis...and demonstrates a serious lack of understanding of the issue."[148] The strength of this rebuke is an indication of just how far apart the AIHC and OSHA were on this issue. It is important that many scientists employed in the businessworld were generally supportive of the policy. In fact, some were included in internal OSHA strategy meetings.[149] If the preamble is an accurate presentation of the testimony, it would appear that the AIHC was isolated on these and other issues.

Human Data vs. Animal Data

There is little argument over the fact that the strongest evidence for establishing the cancer-causing ability of a substance is through human experience. If rates of cancer are known to be higher in an exposed population, and if all other confounding factors can be controlled (including socio-economic status, age, smoking history, reporting errors, selection and recall biases, water supply, diet,

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[147]45 FR 5028

[148]45 FR 5033

[149]Interview with Anson Keller, Ibid. Keller stated that the scientists from the businessworld did not play a much different role than the other government scientists with which OSHA consulted.

medical history, etc.), then it seems certain that the substance is in fact a carcinogen.

However, due to its lack of sensitivity, epidemiology has been a weak tool in identifying non-carcinogens, and OSHA took the position that positive animal data should therefore supersede negative epidemiological data. Scientifically, it is always difficult to prove a negative (i.e., that something is not carcinogenic. In other words, if animal tests say the substance is a carcinogen, but we haven't seen increased cancer rates in exposed humans, should we regulate the substance as a carcinogen? Arsenic, asbestos, benzene, and vinyl chloride are all examples of substances that were the subjects of "false negative" epidemiological studies. In fact, one of the main reasons asbestos was finally identified as a cancer-causing substance was due to its ability to produce an extremely rare form of cancer, mesothelioma, which was more easily detected.

Industry generally took the position that epidemiological studies should play an important role, and were useful in estimating the "upper bound" of risk posed to humans by a particular substance. OSHA modified its final rule so that such evidence could be considered, but still held that positive animal data was sufficient for regulatory purposes.[150]

One or Two Tests

The quality of animal testing protocols was also debated. There was some concern voiced about the original proposal, which could have been interpreted to require regulation even if a poor-quality study showed carcinogenic potential. OSHA modified its proposal to require two tests for confirmation, although it noted that poor-quality tests were more likely to result in a negative finding. At this

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[150]45 FR 5058

time, the EPA felt that professional judgement could be used, and that only one high quality positive animal study was sufficient.[151]

The reliance on animal testing was a significant departure from past practice, and finds expression in later OSHA regulations, such as the relatively new Hazard Communication Rule implemented in 1985. The rule requires employers to identify as carcinogenic those substances which have been found to cause cancer in animals. Conclusive evidence of cancer causation in humans is no longer required (although there is still much debate on the question). OSHA has indicated recently that containers of carcinogens which have inadequate data in humans, but sufficient evidence in animals (IARC Group 2B), do not need to be labeled as a carcinogen. The positive animal testing information does have to appear on a Material Safety Data Sheet, however.[152]

The Threshold Question

Industry representatives generally argued that a Permissible Exposure Limit (PEL) greater than a lowest feasible limit should be set based on the fact that a practical threshold, or safe dose, could be calculated below which the likelihood of developing cancer was vanishingly small. This was dubbed the "you should live so long" theory during the rulemaking hearings. Essentially, this view held that a temporal relationship seen in animal studies could be applied to humans. The relationship shows that a decreasing dose results in a longer period of time before tumors become evident. If a dose could be identified that would cause tumors after

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[151]45 FR 5105

[152]OSHA Instruction CPL 2-2.38A, May 16, 1986, Amended by CPL 2-2.38A CH-1, July 18, 1986, published by Bureau of National Affairs, Occupational Health and Safety Reporter Reference File, p. 31:9515

a time period greater than a human's lifetime, then that dose should be considered permissible.

The problem with this view is that it does not consider the uncertainties present in animal testing:

> But the issue is not thresholds or no thresholds; it is one of adding a new carcinogen to a pool of present carcinogens. I would suggest, therefore, that there may well be thresholds with carcinogenic substances when given to a very clean animal in an environmentally controlled situation, that is, when there are few or no other carcinogens present: this is what the experimental oncologist tries to create in the standard laboratory animal test system--a clean animal of known and homogeneous genetic background and no known carcinogens living in sterile filtered air. The human population is different, however. The mouse doesn't smoke or breathe hydrocarbons or sulfur oxides from fossil fuels, doesn't drink, doesn't take medicine, doesn't eat bacon or smoked salmon, but man does.[153]

Because humans are exposed to a variety of substances, OSHA concluded that "the concept of thresholds [is] irrelevant and inapplicable to the determination of human hazards or risks."[154]

Scientific Uncertainty and Prudence

OSHA noted that animal tests had also been far from reliable in the past. The case of thalidomide was cited, where it was found that humans were 60 times more sensitive than mice, 100 times more sensitive than rats, 200 times more sensitive than dogs, and 700 times more sensitive than hamsters to this particular medication. In addition, no animal studies have ever conclusively shown inorganic arsenic to be carcinogenic, even though it is a known human carcinogen.[155] While OSHA considered the idea of specifying protocols for animal and other toxicity

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[153]Statement by David Rall, 45 FR 5137

[154]45 FR 5137

[155]45 FR 5137

testing, it concluded that the state of knowledge was advancing too rapidly in this field for such protocols to be of use.

How to proceed with regulation in the face of this uncertainty may have been the most difficult of all questions and remains controversial today. The AIHC was highly critical of OSHA's decision not to attempt to differentiate various carcinogens on the basis of "potency." The FDA stated that quantitative risk assessment was a necessary part of decisionmaking, and the EPA concurred. While some of this disagreement among agencies can be laid to different language in the relevant statutes, much of it is due to the unique nature of the occupational environment. The experience with beta-naphthylamine demonstrates the difference.

> Beta-naphthylamine for workers who have been exposed to that compound for over a five year period causes 100 percent bladder cancer. Now, you would never have predicted that from the animal tests. You would have predicted that it is a carcinogen, but you would not have predicted its potency. I wish we had test systems in which we could predict potency, but we do not."[156]

The essential point is that prudence is important in managing occupational risks, especially since exposures in occupational settings are usually orders of magnitude higher than they are in the environment. This is yet another example of how a risk management decision affected a risk assessment procedure. Attempting to quantify the risk involved for humans from animals is subject to uncertainties because of differences in:

1. The number of animals tested (typically 100-1000); the human population in this country is between 200 million and 300 million
2. Environmental differences - heat, light, radiation, etc.
3. Absorption differences
4. Distribution and storage differences
5. Metabolic differences

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[156]Statement by Dr. C. Harris, 45 FR 5182

6. Differences in excretion and reabsorption

7. Receptor sites

In short, attempting to put numbers on acceptable exposures to carcinogens in the workplace is likely to be especially problematic; setting PEL's above the lowest feasible limit would essentially be a return to the way regulation was conducted in the past: The only test for adequacy is a body count.

Government or Independent Scientists

OSHA decided to rely largely on government scientists in exercising professional judgement regarding proper assessment of toxicity testing and proper classification of individual substances. The AIHC wanted these advisory committees to be composed, at least in part, by "independent" scientists; the advisory committees were also to be autonomous.[157] Presumably, this would allow business a greater voice in the classification and regulation of specific substances. However, OSHA decided that this would constitute an illegal transfer of authority from OSHA to a non-governmental panel, that it would be inefficient and result in needless delays, that it would not ensure the protection of workers, that it would not be accountable, and that Congress rejected the concept of independent boards when it gave authority for standard setting to the Secretary of Labor.[158] Of course, Congress did allow initial use of consensus standards, which were developed by independent (private) organizations, but this was only a means to get OSHA on its feet.

This issue has resurfaced today as OSHA attempts to update its Permissible Exposure Limits with 1988 Threshold Limit Values. TLVs are consensus standards

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[157]45 FR 5203

[158]45 FR 5203

set annually by the American Conference of Governmental Industrial Hygienists, a professional group. Some have argued that the TLVs are established behind closed doors and are excessively influenced by business interests.[159] The role of the National Institute for Occupational Safety and Health is also relevant here, and will be examined in greater detail later.

Categorization

The AIHC did support the general view that generic standards were the only feasible way to regulate chemicals, although it then proceeded to attack nearly every aspect of the policy. For example, it criticized the effort to categorize substances, the heart of the standard. To put it simply, Category I was reserved for those substances confirmed to be carcinogenic. Category II was reserved for those substances for which the evidence was "suggestive" and still inconclusive. The AIHC held that this would "freeze science," arguing that once a substance had been categorized, new evidence would be less likely to be generated. However, one scientist testified that:

> I believe most scientists will be happy to see the introduction of something like Category II, recognizing that some experiments give inconclusive results and allowing us to escape from the dilemma of having to assign all chemicals into "Yes" or "No" categories.[160]

The trend toward more categories has continued. The International Agency for Research on Cancer (IARC) now has no less than four categories in which to classify carcinogens:

> Category 1 - There is sufficient evidence to support a causal association between the exposure and cancer.

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[159]"Study Charges Corporate Influence on TLVs, Calls for International Effort to Set Guidelines," BNA Occupational Safety and Health Reporter, October 28, 1987, p. 871

[160]45 FR 5206

Category 2 - Includes exposures which are probably carcinogenic to humans.

Category 2A - Usually reserved for exposures for which there is at least limited evidence of carcinogenicity to humans
Category 2B - Cases where there are inadequate data in humans, but there is sufficient evidence in animals.

Category 3 - Chemicals which cannot be classified as to their carcinogenicity in humans.

The primary purpose of the Category II cited in the OSHA cancer policy was to draw attention to the lack of information and promote further research, quite the opposite from "freezing science." Anson Keller stated that the final version contained too much regulation for Category II substances, which in the original proposal would have been controlled through cheaper means, such as improved work practices, better material control, etc.[161] As Table 2.1 shows, the requirements for both categories were extensive.

Two other categories (III and IV) were dropped in the final version of the regulation, since it was thought that they would be wasteful of resources. Category III was to include those substances for which evidence was inconclusive and Category IV was for those substances not used in American industry.

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[161]Interview with Anson Keller,Ibid.

Table 2.1 OSHA Carcinogen Categories

Category	Definition	Requirements
I	Meets the definition of potential occupational carcinogen in: 1. Humans 2. A single mammalian species in a long-term bioassay which is in concordance with some other scientifically evaluated evidence 3. A single mammalian species in a long-term bioassay where OSHA determines that supporting evidence is not necessary.	1. Notification of use. 2. PEL set as low as as feasible, through engineering and work practice controls. If a substitute is available, no exposure is permitted (banned). 3. Exposure monitoring 4. Regulated areas 5. Compliance plan 6. Respirators 7. Protective clothing, etc. 8. Housekeeping 9. Waste Disposal 10. Wash Facilities 11. Medical surveillance 12. Employee training 13. Signs & Labels 14. Recordkeeping
II	1. Same as Category I, except the evidence is found to be "suggestive." 2. Same as Category I, except the evidence does not have supporting evidence from other tests	1. Same 2. PEL set on a case-by-case basis, to be met mainly through engineering and work practice controls 3. Same 4. No regulated area 5. No compliance plan 6. Same 7. Same 8. Same 9. Same 10. No wash facilities 11. Same 12. Same 13. No signs or labels 14. Same

A Potential Occupational Carcinogen is defined in the policy as:

> any substance or combination of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals.[162]

In a recent interview, John Pendergrass stated that this definition does not agree with other commonly used definitions, and that this was one of the main reasons the policy continues to have low priority. However, he could not state what the principal differences are.[163]

Prioritization: How Industry Used "Good Science" As A Cover for Delay

At the urging of economists, the AIHC, and others, OSHA agreed that it was important to prioritize which substances would be classified first. In the preamble to the 1980 standard, OSHA stated that priority-setting should not slow the important process of reducing human exposure to potential carcinogens. Most priority setting systems were thought to be far too elaborate, leading to "paralysis by analysis."[164]

OSHA initially chose to publish a list of candidate substances, with final regulations based on "model standards," to be implemented no more than a year later. The original proposal provided for establishment of an Emergency Temporary Standard, but this "automatic trigger" was dropped in the final standard to ease criticisms of lack of flexibility. However, even this was not the prioritization

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[162]45 FR 5283

[163]Interview with John Pendergrass, American Industrial Hygiene Conference, San Fransisco, California, May 1988

[164]45 FR 5210, January 22, 1980

scheme industry had in mind. The AIHC regarded the candidate lists as a sort of blacklist and de facto ban, even though OSHA pointed out that the candidate list was not a final judgement, and that no model standard would have been applied without the opportunity for public comment. By calling for prioritization, but then objecting to actual publication of the priority list, industry's hidden agenda of delay became more evident.

While there were press reports that OSHA intended to name over 100 chemicals that would fall under immediate model standard regulation,[165] the priority list for both categories was not expected to name more than ten. The full candidate list was expected to include 187-488 substances, while the shorter priority list (of about 10 substances) was to be published every six months.[166] One such candidate list of 106 substances did appear late in 1980,[167] but it was never acted upon, and the model standards were never tested. A storm of controversy erupted as businesses argued that their products had, in effect, been banned without public hearings, even though the Priority List was for Potential carcinogens. As far as industry was concerned, mere appearance of a chemical on any list in the Federal Register amounted to regulation. There are also reports that a great deal of OSHA staff time was involved in compiling the list.[168] Apparently, no official Priority List was ever published, and the model standards were never applied.

Economic Analysis

[165]Dewars H: "OSHA Details Plan to Control Worker Exposure to Carcinogens," Washington Post, October 4, 1980, p. A7

[166]45 FR 5205

[167]45 FR 53672, August 12, 1980

[168]Interview with Anonymous National OSHA Staffer, Ibid.

The original proposed regulation called for the determination of the lowest feasible occupational exposure limit, while the final version added the words, "including technological and economic considerations."[169] This is in keeping with OSHA's distinction between assessing economic feasibility and cost-benefit analysis described earlier. Economic feasibility means an assessment of the impact of a proposed standard on various industries. Here, the decision to regulate has already been made. However, under cost-benefit analysis, the decision to regulate is not based on health effects, but on whether the estimated benefits outweigh the estimated costs.

Generally, both the government economists in Schultze's Regulatory Analysis Review Group and OSHA agreed that carcinogens should be regulated due to their "externality-generating nature," since "externalities result in an inefficient allocation of society's resources because market prices fail to reflect the social cost of production."[170] However, AIHC economists and others from the American Petroleum Institute argued that OSHA was attempting to create a "risk-free" society, which is both impossible and wasteful. Instead, the economists argued, the costs and benefits of each regulation should be determined to quantify the "reasonably necessary" level of risk. Exposure levels for Category I substances would therefore not be set at the lowest feasible level, but some level where the risk was low enough to be acceptable to society at large.[171] To this day, NIOSH has held to the doctrine of lowest feasible exposure, although they have recently completed a quantitative risk assessment. The economists also wanted the engineering control

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[169]45 FR 5235

[170]45 FR 5235

[171]45 FR 5237

specifications removed from the model standards in favor of more performance-oriented provisions (such as respirators).

> AIHC believes that the record strongly supports the conclusion that OSHA should undertake a cost/benefit analysis as part of the regulatory process to determine the level of control. This may not necessitate an elaborate cost/benefit analysis but it does mean that OSHA will have sufficiently identified the societal costs and benefits so that it can more reasonably determine an acceptable level of risk--the reasonably necessary level--in setting particular standards.[172]

In attempting to define what such a level would look like, Dr. Nicholas Ashford of MIT testified about a concept he called "minimization of regret." Basically, this means that society prefers actions which prevent major disasters, even if regulations would in retrospect be stricter than absolutely necessary.[173] Of course, this represents an unacceptable inefficiency to most economists. If Ashford is correct, then there are occasions when society prefers inefficiency over accepting risks.

The Regulatory Analysis Review Group (RARG), which was headed by Charles Schultze, apparently never agreed to the generic approach, insofar as economic analysis goes. In their testimony, they recommended the weighing of costs and benefits of different regulatory approaches for each specific substance,[174] which is certainly not a generic approach, and certainly not a prescription for speeding up rulemaking. In any case, none of the principals involved in the 1980 formulation of the policy recalls any further substantial interference from the economists, possibly due to the general nature of the policy,[175] and a decision by the economists to fight against individual standards, waiting for implementation of the cancer policy to decide how to respond.

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[172]45 FR 5246

[173]45 FR 5246

[174]45 FR 5237

[175]Interviews with Eula Bingham and Anson Keller, Ibid.

The seeming neutrality of cost-benefit analysis was also criticized during the hearings with regard to equity considerations. In occupational health and safety matters, the benefits are likely to accrue to one group (industrialists, and perhaps consumers in the form of lower prices--although consumers may also have some exposure) while the costs are borne by another group (workers).

> Maximizing social welfare should not necessarily be equated with optimizing social welfare. Equity and economic efficiency are sometimes conflicting goals. As a decision tool, cost-benefit analysis can be useful in identifying the nature of the trade-offs; as a decision rule, it is useless. Regulation of toxic substances is an expression of social policy, not economic policy, and the social decision does not end with internalizing the social costs of producing and using chemicals, followed by equating costs and benefits at the margin.[176]

RARG did criticize the Snell Report, which was funded by the AIHC to estimate the total costs of the carcinogen policy. "There are a number of major methodological problems with the...Snell Report which makes it impossible to place great confidence in its results." The methodological problems involved the use of scaling factors and a very small group of 7 substances and 8 pesticides to arrive at total cost figures of $9 billion - $88 billion in capital costs and $6 billion - $36 billion in annual costs caused by generic regulation of all carcinogens. More fundamentally however, the Snell Report did not calculate the costs involved in the non-regulation of industrial carcinogens, such as premature death, family suffering, medical costs, government transfer payments, etc.[177] Many of these types of costs are intangible, or at least extremely difficult to quantify. In practice, economists simply choose to ignore them, as the author of the Snell Report did.

OSHA concluded that the lowest feasible limit of exposure should be set for carcinogens, not levels set based on acceptable risk, by means of cost-effectiveness analysis or cost benefit analysis. The analytical techniques were too crude,

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[176]Statement by N. Ashford, 45 FR 5249

[177]45 FR 5239

efficiency criteria alone were not appropriate because equity considerations were ignored, and finally, the OSHA Act required the lowest feasible level since no safe level of exposure can be determined.[178] The Supreme Court's decision on the benzene standard would change this.

Favorable Review By The White House

How was the cancer policy handled at the White House? A White House memo dated August 11, 1979 indicates that the OSHA carcinogen policy was one of the "big five" regulations singled out by "Stu, Charlie, Fred, and McIntyre," primarily due to its potentially large price tag. The Administration handed it over to the Regulatory Council, regarding it as an interagency affair, although they noted that the document "needs work."[179] On October 1, 1979, Si Lazarus noted that the Regulatory Council cancer policy "leaves much room to the agencies with respect to many of the interesting issues about how tight to turn the screw. We will have to see what EPA and OSHA do with that room."[180] By January 15, 1980, however, another White House memo supported the final OSHA regulation, calling it "light years ahead of the original proposal."[181]

Even Eizenstat and Schultze gave a favorable review. They wrote to the President that the OSHA and DOL staffs

> ...could not have been more cooperative in working with other interested agencies and with our staffs in shaping the final regulation...although neither industry nor labor is likely to be completely satisfied with the final result.

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[178]45 FR 5239

[179]White House Central File, Subject File, Health 4-2, Box HE-7 Memo for Stu Eizenstat from Si Lazarus, August 11, 1979

[180]Memo from Si Lazarus to Stu Eizenstat, October 1, 1979, White House Central File, Box HE-7, File Health 4-2

[181]Memo for Eizenstat from Ron Lewis, January 15, 1980, White House Central File, Box HE-7 File Health 4-2

> We believe the process worked well here; it emphasized extended discussion and peer criticism, rather than confrontation."[182]

However, the AIHC later joined in an industry-wide suit challenging OSHA over the "lack of scientific validity," contending "that the OSHA regulation is of unprecedented sweep and generality."[183] AIHC listed 5 objections to the final rule in a meeting with White House staffers:

1. The OSHA scientific advisory panel would be composed of government scientists, not independent experts
2. The use of risk assessment would be limited to prioritizing, not in establishing control levels
3. No threshold dose for carcinogens was allowed
4. There was no distinction between strong and weak carcinogens (potency)
5. The model standards dictated engineering controls instead of performance standards.[184]

Apparently, White House staffers finally turned a deaf ear to the AIHC, in spite of their earlier close working relationship. Industry then turned to the courts, where the American Petroleum Institute asked the US Fifth Circuit Court of Appeals to review the regulation, even before it had been announced.

The Reagan Administration: Withdrawal

Before the OSHA cancer policy could be fully implemented, a new administration with a radically different perspective toward regulation took office. Initially, the Reagan administration planned to withdraw the regulation in piecemeal

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[182]Memo to the President from Eizenstat, Kahn, and Schultze, January 15, 1980, White House Central File, Box HE-4, File HE 1-2 4/18/79 - 1/20/81

[183]American Petroleum Institute, et al. v. OSHA, et al. nos. 80-3018 et al. (Fifth Circuit)

[184]Bernick Papers Box 10, OSHA Carcinogens [3]

fashion.[185] No priority list was ever published after the first candidate list was published on August 14, 1980. An administrative stay of these listing requirements was published on January 4, 1983.[186] Apparently, there were also plans to remove the entire standard, but this effort was never accomplished.

Thorne Auchter, who headed OSHA during the early years of the Reagan administration, characterized the regulatory stance of the previous Carter Administration as being extremely pro-regulatory. Carter's concept of producing regulations only when needed and removing unimportant rules was replaced by a concept of producing regulation only when the evidence of need was absolutely indisputable. Auchter recognized that such evidence was not available for most carcinogens, and initiated action on only one during his tenure--an Emergency Temporary Standard for asbestos.[187] In an interview he stated that there are "only two 100% proven carcinogens--asbestos and cigarette smoke."[188] In short, the level of proof required by this administration was much higher.

The Benzene Decision: Throwing Water on the Dying Embers

Some of this reticence was due, at least in part, to the Supreme Court ruling on benzene,[189] which was handed down at the end of the Carter Administration. A badly-divided court ruled that the agency must make a factual finding that a

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[185]"OSHA Planning Cancer Policy Withdrawal; Complete Rewrite Favored Over Amendment," BNA Occupational Health and Safety Reporter, Vol 12, No. 27, Dec. 2, 1982, p. 539

[186]48 FR 241, January 4, 1983

[187]The ETS was issued on Nov. 4, 1983 (48 FR 51086), which was vacated by the Fifth Circuit Court on March 7, 1984 (Asbestos Information Association v. OSHA, 727 F. 2d 415)

[188]Interview with Thorne Auchter, February 3, 1988

[189]International Union Department, AFL-CIO v. American Petroleum Institute, 448 US 607 (Supreme Court, July 2, 1980

significant risk is present and will be eliminated or significantly reduced by regulation.

Four of the justices argued that OSHA did not present sufficient evidence to show that reducing benzene exposures from 10 ppm to 1 ppm was necessary, and that the current PEL of 10 ppm placed employees at "significant risk." Four other justices protested this view, writing that,

> ...the plurality [the other four justices] ignores the plain meaning of the OSHA Act of 1970...The unfortunate consequence is that the Federal Government's efforts to protect American workers from cancer...may be substantially impaired...According to the plurality, a standard is not "reasonably necessary or appropriate" unless the Secretary is able to show that it is "at least more likely than not" that the risk he seeks to regulate is a "significant one." Nothing in the statute's language or legislative history, however, indicates that the "reasonably necessary and appropriate" language [in the OSHA Act] should be given this meaning.[190]

The deciding vote belonged to Justice Rehnquist, who argued that, due to its vagueness, the OSHA Act was an invalid delegation of authority by Congress.

There are numerous contradictions in this ruling. For example, while it said OSHA should not have relied on assumptions and theories to show risk at 10 ppm, the plurality also said OSHA was "free to use conservative assumptions in interpreting the data with respect to carcinogenicity." The plurality also mentioned the OSHA cancer policy in a footnote. It claimed that OSHA might go too far in regulating American businesses, and that a decision in favor of OSHA would impose enormous costs that might produce little, if any, discernible benefit. The footnote says, "OSHA's cancer policy indicates that this possibility is not merely hypothetical." Even though the vote was so close, the decision is of tremendous significance, since it was the first time the Court had ruled on risk assessment. Since the ruling, all environmental regulations now develop some sort of quantitative risk assessment as part of the record.

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[190]IUD v. API, 448 US 607 (1980)

In January, 1981, OSHA deleted the provisions which required the PEL to be set automatically at the lowest feasible level for Category I potential carcinogens, and also those provisions which limited the type of evidence that could be considered. In their place, OSHA proposed to set the exposure limit at the lowest feasible limit which is necessary to eliminate significant risk.[191] This represented the Carter administration's last-ditch effort to make the cancer policy conform to the benzene decision. However, the Reagan administration launched a full-scale review of the cancer policy amendments, and published an advance notice of proposed rulemaking to overhaul the policy.[192]

The effect of the benzene ruling on the OSHA cancer policy was severe, especially in the hands of individuals predisposed against regulation. Rather than attempt to incorporate risk assessment into the cancer policy, Auchter allowed the policy to remain dormant. His perception of regulation in general is that much of it was driven by litigation, the very thing that the policy was intended to prevent. He believes that the courts began to issue rulings on the substance of a given agency action. A more proper role for the court would be to rule only on issues of due process, he believes.[193] Of course, if he had chosen to implement the cancer policy, the courts may have had more of a procedural foundation on which to review cases. The absence of a generic cancer policy explaining how the agency had reached a decision to regulate specific substances may have allowed the court to dabble further in the area of scientific expertise. The substantial scientific record amassed in support of the policy may have also made it more difficult for the Justices to rule on matters of scientific knowledge. Of course, if the court felt

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[191]46 FR 4889, January 19, 1981

[192]47 FR 187, January 5, 1982

[193]Interview with Thorne Auchter, Ibid.

that the cancer policy was simply unreasonable, it may have prompted further action in the Congress. It is worth emphasizing that the vote was extremely close, and the ruling fairly muddied.

This orientation towards reacting to court rulings has had a detrimental effect on staffing the agency. Auchter indicates that he had considerable difficulty attracting senior health officials to join the agency, with many considering it a "no-win" proposition from a career standpoint, because of the numerous enemies made in the course of working at the agency. In fact, Auchter believes one may have more influence from outside the agency than from inside the agency.[194] Eula Bingham has charged that the agency is now in "shambles," not so much due to the litigious environment as to other factors:

> The people who are really concerned...who really did the job in the face of adversity, if they possibly could leave have gone...There's no spirit at OSHA. There's no self-esteem. There's no commitment to standards and enforcement, [although] I do believe there are a few dedicated people [left].[195]

The number of OSHA inspectors declined from 1,328 in 1980 to 1,044 in 1987. Perhaps more importantly, the type of inspection shifted from an emphasis on comprehensive physical inspections of worksites to inspections of records only. In 1986, 4,619 records inspections were conducted. Reflecting this change, the agency has recently levied very large fines against Chrysler Corporation and IBP, Inc. (a meatpacking firm) of $1.57 million and $2.59 million, respectively.[196] In both cases, the fines were for failure to maintain written records of injuries and illnesses sustained by employees. These records must be accurate if the agency is to target

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[194]Interview with Thorne Auchter, Ibid.

[195]Speech by Eula Bingham before Worker's Education Local 189, Cincinnati, Ohio, November 21, 1987

[196]Glaberman, W: "Is OSHA Falling Down on the Job?" New York Times, August 2, 1987, p. F1

its inspections successfully at only the most hazardous industries, as the Reagan Administration intended. Of course, there is an incentive for business to under-report injuries and illnesses to avoid an inspection, so OSHA has recently retreated from the targeting system. Now, at least 10% of all inspections are conducted in general industry, not only in the high hazard area.

What has been the effect of slower standards setting and the orientation toward records-type inspections? It is quite difficult to show how increased judicial review and reluctance to set standards has affected statistical measures of safety and health. Occupational injury and illness rates increased slightly in 1984, and have remained higher than in 1982 and 1983 (see Table 2.2), although there are a number of other possible confounding explanations. These include changes in employers' understanding of reporting requirements, improved workers' compensation benefits (which may mean workers are more likely to make claims), business cycles, and a shift in employment from hazardous industry to less hazardous service and white collar jobs.[197] In spite of these caveats, one can not rule out the hypothesis that relaxed enforcement and standards-setting agendas have contributed to the interruption in the decline of injury and illness rates. The increase in 1984 was the biggest in the agency's history.[198] Overall, however, the rates have declined dramatically from the rate in 1973 (11.0/100 workers), and remain below the levels seen during the Carter administration, providing at least suggestive evidence that an activist OSHA has in fact made a difference.[199]

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[197]Mendeloff, J: "The Hazards of Rating Workplace Safety," Wall Street Journal, February 11, 1988, p. 30

[198]Glaberman, "Is OSHA Falling Down on the Job?" Ibid.

[199]"NIOSH Director Praises OSH Act, Cites 'Clear Evidence' of Law's Impact," Occupational Safety and Health Reporter, Bureau of National Affairs, September 23, 1987, p. 747 "Millar [NIOSH Director] cited worker fatality figures as evidence of the law's impact. He said that over 14,000 workers were killed in 1968...by

Table 2.2 Occupational Injuries and Illness Incidence Rates per 100 full-time workers, 1978 - 1986

1978	9.4
1979	9.5
1980	8.7
1981	8.3
1982	7.7
1983	7.6
1984	8.0
1985	7.9
1986	7.9

Source: Bureau of National Affairs and Bureau of Labor Statistics

Carcinogen Policies at Other Agencies During the Reagan Years: Increasing the Level of Acceptable Risk

While the carcinogen policy languished at OSHA, other agencies proceeded to make changes to their carcinogen guideline policies. Much of the work involved attempts to increase the levels of acceptable risk for specific substances. For example, in 1982, the EPA proposed to increase the previously-accepted doctrine of tolerating a statistical risk of 1 cancer case per million people. In the case of ethylene bisdithiocarbamate fungicides, EPA said the risk of contracting cancer from food residues would be between 5 in 10,000 to 5 in 100,000. The occupational risk of contracting cancer would be much higher, between 1 in 100 and 9 in 100,000. Nevertheless, the agency granted a 2-year extension for continued use of about 27 million pounds per year.[200]

Even more controversial was the attempt by EPA's John Todhunter, an assistant administrator for the Office of Pesticides and Toxic Substances, to divide

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1984...statistics showed that 6,496 workers died in workplaces..."

[200]"EPA's High Risk Carcinogen Policy," Science, Vol. 28, December 3 1982 p. 975-978

suspected carcinogens into "genotoxic" and "epigenetic" categories. The theory stipulates that genotoxic carcinogens directly affect a cell's DNA, resulting in the "one-hit" that can lead to tumor formation (recent theories have stipulated that at least 2 "hits" are required in the DNA molecule to produce a tumor). Epigenetic carcinogens produce tumors through other mechanisms, for which the body may have defenses. The effect of the proposed classification scheme would have been to permit greater exposure to the epigenetic compounds, since a safe level of exposure was at least theoretically possible. However, a number of other scientists protested that the ability to distinguish between the two types was poor, and could not be used as the basis for policy. A leading cancer researcher stated,

> Their theories have been shot down as far as scientific support, yet we're seeing them implemented in individual decisions...If what they're trying to do is to lower the burden of regulation to meet economic goals, then they should open it to the public and see if the public is willing to take the additional risks.[201]

The final blow to this classification scheme was the experience with dioxin (2,3,7,8-tetra-chlorodibenzo-p-dioxin), a "classic epigenetic carcinogen."[202] This substance is such a potent carcinogen in animal tests that it fueled public fears, leading to the evacuation of a small town in Minnesota.

Politically, these moves were dealt a severe blow when the top administrator of EPA, Anne Burford and an assistant, Rita Lavelle, were accused of mismanaging the agency's program to clean up hazardous waste sites. Both officials resigned and one was sent to jail. Congress initiated oversight hearings, and the House Energy and Commerce Committee stated that "In the past two years, the Reagan

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[201]Frederica Perrera, quoted in National Journal, Ibid.

[202]Ellen Silbergeld, quoted in Wines M: "Scandals at EPA May Have Done in Reagan's Move to Ease Cancer Controls, National Journal p. 1269

administration has shown itself to be soft on cancer."[203] Norton Nelson, chairman of the board of counselors to the National Toxicology Program, said that the Reagan Administration was "covertly" abandoning long-accepted scientific bases for cancer regulation.[204]

Recently, this issue has been revived in slightly different format. New models of carcinogenesis theorize three stages: initiation, promotion, and progression. If a substance can be identified as a promoter, then theoretically, it may have a threshold (safe) dose, since it must be present in fairly high concentrations to allow an initiator to progress to tumor formation. However, reliable analytical techniques to identify the different types of carcinogens are still wanting.

The trend toward lowering estimates of risk levels associated with exposures to carcinogens continues today. For example, the EPA has recently estimated that the risk of skin cancer from arsenic is one-tenth of the 1984 estimate. Dioxin is now thought to pose one-sixteenth of the risk estimated in 1985. Risk estimates for methylene chloride were reduced by nearly 90 percent.[205] Dioxin, asbestos, and cigarette smoke are thought to be promoters, and some scientists believe that safe threshold doses can be identified through more sophisticated use of animal testing results. Others however, including Barry Commoner and Marvin Schneiderman (former associate director of the National Cancer Institute) have stated that the reassessment is not based on current scientific understanding. Commoner has called it "ludicrously bad science," while Schneiderman maintains that the new information

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[203]Wines M: "Scandals at EPA May Have Done In Reagan's Moves to Ease Cancer Controls," National Journal, June 6, 1983, p. 1264

[204]Wines, M: "Scandals at EPA May Have Done in Reagan's Moves to Ease Cancer Controls," Ibid.

[205]Shabecoff, Philip, "EPA Reassess the Cancer Risks of Many Chemicals," New York Times, January 4, 1988, p. 1

has not in fact been worked into risk assessment models used by EPA.[206] There have also been reports showing that dioxin alone has been capable of causing tumors (i.e., that it acts as an initiator as well as a promoter).[207] Of course, since conservative assumptions have been used in the past, it is possible that as we learn more, we will find that the risks are not as bad as originally thought. While this seems reasonable, the actual practice has been to lower acceptable exposure limits like TLVs and PELs when new evidence is presented, not raise them. Thus, in spite of conservative assumptions, new research more often than not shows that chemical exposures are riskier than we thought.

The issue of quantitative risk assessment will be examined in the next chapter. It is worth noting the economic effects of the new risk reassessments, however. Syntex Inc., which currently has about $15 billion in lawsuits resulting from the Times Beach dioxin episode, indicates that it could save $11 million in cleanup costs if the new risk assessment were used. Dow Chemical, Monsanto, and Hercules, Inc. would also save substantial sums of money due to lower cleanup costs.[208]

Cancer risks were also the subject of a recent court ruling on use of carcinogenic food dyes. The FDA argued that the risks posed by these substances was as low as one in 19 billion, and that the risk was "so trivial as to be effectively no risk." The court stated that the concern over carcinogens in Congress and the public "...resulted in a close focus on substances increasing cancer threats and a willingness to take extreme steps to lessen even small risks." The

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[206]Hays, Laurie, "Proposals from Federal Agencies to Ease Dioxin Standards Renew Debate on Risk," Wall Street Journal, January 27, 1988

[207]Bernard Weinstein quote in Wall St. Journal, Ibid. quoted as saying dioxin alone has been shown to produce tumors in some experiments

[208]Hays, Laurie: "Proposals From Federal Agencies to Ease Dioxin Standards Renew Debate on Risk," Ibid.

court said it was up to Congress to determine if this was an example of an undesirable consequence of the Delaney Clause.[209] Clearly, this is a far cry from the Benzene Decision, where the court focused on reasonableness and significant risk.

The OSHA cancer policy was scheduled for an update in January, 1988. An OSHA staffer has indicated that no real progress is expected until October[210], and many other observers feel that the election year will produce bureaucratic inertia.[211] However, the AIHC is pursuing the matter, and hopes to provide the push to have OSHA revise the policy before a new administration takes office.

Conclusion: The Continuing Struggle Between Regulators and Economists

In this chapter, several conclusions can be drawn from the historical experience of the OSHA cancer policy:

1. Lawyers and scientists developed an uneasy but productive relationship to formulate the carcinogen policy. Lawyers realized that continuous relitigation over certain cancer principles was not productive. Scientists realized that there would continue to be large gaps in our understanding of cancer for the forseeable future. Together, these two groups achieved a broad consensus on how uncertain scientific knowledge can be used to make cancer regulatory policy.

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[209]Associated Press, "Appeals Court Rejects FDA decision to allow cosmetic dyes tied to cancer." Atlanta Journal Constitution, October 24, 1987

[210]Interview with Anonymous OSHA Staffer, Ibid.

[211]BNA Special Report, "Hazard Communication, Recordkeeping, Z-Table Project Head OSHA Agenda in Shadow of Election-Year Malaise," Occupational Health and Safety Reporter, January 6, 1988, p. 1240-1252

2. The relationship between economists and regulators has not achieved this type of consensus, and has been marked by bitter struggle. This struggle has pitted those who wish to minimize the costs borne by industry against those who wish to maximize public health. As arbiter, the courts have often sent conflicting signals as to what is "reasonable." In spite of the cotton dust episode, economists have largely emerged victorious. Sweeping generic regulation of carcinogens has given way to incrementalism (i.e. substance-specific regulation).
3. An important tactical element in winning acceptance for the cancer policy involved disarming the business community by removing unimportant safety rules. Since there are unlikely to be many more of these left on the books, such a scenario may not be easily repeated in the future.
4. The model of a strict separation of risk management and risk assessment appears to break down. In practice, the two appear to mix extensively, but without an established process. It is worth noting that the testimony given during typical rulemaking does not encourage discussion and debate among the participants (i.e., there is no negotiating process). Risk-averse or risk-tolerant management assumptions have affected risk management principles (e.g. benign vs. malignant tumors, genotoxic vs. epigenetic carcinogens, etc.).
5. Individual personalities matter. President Carter's practical experience with respirators appeared to have swayed a close decision. Eula Bingham was willing to take risks and proceed in the face of uncertain scientific information. However, Thorne Auchter practiced more caution and demanded a higher level of certainty, perhaps even higher than the courts would have demanded, before taking action.

6. Organized labor was conspicuously absent from the struggle over the cancer policy, while business was extremely well-organized. The AIHC played a highly visible role, and appeared to be well-connected with White House staff members. Organized labor submitted testimony, but did not attempt to publicize the issue, as they did with the right-to-know standard. Nevertheless, the AIHC appears to have been isolated during much of the rulemaking proceedings, perhaps due to Bingham's close ties to organized labor and the supportive testimony of other scientists from the private sector.

CHAPTER III

METHODOLOGICAL AND PHILOSOPHICAL ISSUES

The creation of a comprehensive carcinogen public policy has been stymied in large part by the difficulties associated with allocating resources between two social activities:

1. Promoting further economic development on the one hand, and

2. Controlling exposures to hazardous substances (caused in part by that economic development) on the other. The previous chapter showed that attempts to "rationally" allocate those resources has historically been performed using quantitative techniques such as cost-benefit analysis, cost-effectiveness analysis, and risk-benefit analysis. Although the use of some version of these techniques will clearly need to be included in any new version of the OSHA carcinogen policy (due to previous court rulings), the assumptions, and indeed, the relevance of such analysis needs further investigation if a future OSHA carcinogen policy is to be politically viable.

The sparring between such governmental agencies as the Office of Management and Budget (OMB) and those involved in safety, health and environmental regulation has been the subject of congressional hearings.[212] OMB is widely regarded as having enormous power over decisions made by regulatory and scientific agencies,

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[212]See Senate Governmental Affairs Subcommittee on Intergovernmental Relations Hearings, Jan. 28, 1986 on OMB impact on regulations governing asbestos and grain dust. Also see Sun S: "Food Dyes Fuel Debate Over Delaney," Science, Vol. 229, Aug. 23, 1985, p. 739-741, which says, in part, "...Members of Congress...say...FDA has succumbed to pressure from OMB...The one exception to Delaney is the approval of saccharin, and that was the result of Congressional Mandate.

and is the source of considerable anxiety and fear among regulators, a role shared by its historical predecessors.[213]

Economists often charge that health and safety regulators don't adequately consider the social costs of controlling hazards, implying that society may be unwilling to pay for additional protective measures if the nature of the lost opportunities were truly understood. The regulators counter that OMB lacks the necessary technical expertise, and that the effect of OMB interference is to increase the level of risk and cheapen the value of life.

For example, former Congressman David Obey has stated, "I believe that when you're dealing in questions related to human life, economic costs are irrelevant."[214] Contrast this with George Schultze's view:

> Environmental goals therefore are not the simple consequence of decisions about how clean we want the air and water to be....[They] confront us...with a set of hard choices between environmental quality and other aspects of living standards, in which the more we want of one, the less we can have of the other."[215]

When Morals and Economics Clash

The Limits of Economic Analysis

The application of economic and risk assessment analytical techniques to carcinogen policy yields a host of important philosophical and ethical issues, and may explain why mixed signals have been sent by both Congress and the courts. Do these techniques aid the decisionmaker in thinking rationally about regulatory

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[213]Walsh J and Culliton B: "Office of Management and Budget: Skeptical View of Scientific Advice," Science, Vol. 183, No. 4123, Feb. 1, 1974, p. 392

[214]Quoted in Occupational Hazards, October 1975, p. 49, cited in Regulating Safety: An Economic and Political Analysis of Occupational Health and Safety Policy, by John Mendeloff, MIT Press, 2nd Printing, March, 1980, p. 69

[215]Kneese, Allen and Schultze, Charles, Pollution, Prices and Public Policy, Washington DC, Brookings Institution, 1975, p. 22

alternatives, or do they obscure important, but intangible, considerations from entering the equation at all?

In environmental, health, and safety regulation, there may be occasions when a decision can be judged to be morally right, even though its benefits do not outweigh the costs. As an analogy, consider the case of crime deterrence. If we assume that increased convictions will lead to a reduction in crime, and if the police arrest an innocent person for the purposes of making an example, then the question of whether the benefits outweigh the costs is clearly an inadequate test. In this case, assume that the benefits of reduced crime are much larger than the costs of the person's lost earnings and other contributions to society while incarcerated. If so, then a cost benefit analysis may conclude that imprisonment is desirable, even though the individual is innocent. Of course, most of us would object that an innocent person should never knowingly be convicted. This means that some things are outside the realm of economics. Human rights are an example. Freedom of speech, freedom of assembly, trial by jury, etc. involve the idea that people can expect to be treated in certain ways, regardless of the efficiencies involved. In the previous chapter, a former OSHA administrator compared the right to a safe and healthy workplace, which is guaranteed by the OSHA Act, to other rights. The value of human life, fresh air, and the right not to be exposed to carcinogens without prior consent while working might also be included in this category.[216,217]

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[216]Some of this material is based on Kelman S: "Cost-Benefit Analysis: An Ethical Critique," Regulation, AEI Journal of Government and Society, January/ February 1981, p. 33-40

[217]For an excellent discussion of the centuries-old debate about what should and should not be placed on the market, see Gunnemann, JP: "Justice With Strangers: The Ethics of Exchange," Mimeo from Emory University, Atlanta, GA (Forthcoming in Prism, a theological journal of the United Church of Christ)

Pricelessness

The concept of pricelessness is anathema to cost benefit analysis, since market prices (and sometimes shadow prices) are often used to compare the value of costs and benefits. The method may work best when such prices exist and correlate well with value. Yet clearly there are occasions when prices of any kind are a poor reflection of the value placed on certain things. For example, respect that is purchased at a high market price (e.g. a corporate executive who hires well-paid yes-men), is likely to have a low value. The common wisdom is that one must earn respect, not buy it; the very act of paying for it devalues it. Similarly, the value of sex consummating love is clearly higher than the sex purchased from a prostitute. Yet cost benefit analysis tends to use market prices when they are available.[218]

All this should not lead to the conclusion held by some critics[219] that quantification of certain things is impossible and should not even be attempted. In fact, many economists would agree that policy decisions based only on a strict comparison of costs and benefits would be poor ones.[220] Some mixture of ethics and quantification of risks is used by all of us everyday in choosing various courses of action. Life can never be completely without risk, and the process of weighing relative risks is omnipresent. The essential point here is that prices, which establish what is or is not feasible, can not provide a correct quantification of the

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[218]Kelman, Ibid.

[219]Hare RM: "Contrasting Methods of Environmental Planning," in Goodpaster KE, et al. Ethics and the Problems of the 21st Century, University of Notre Dame Press, Notre Dame, 1979, p. 64-68, cited in Shrader-Frechette, Science Policy, Ethics, and Economic Methodology, D. Reidel, Boston, 1985, p. 153

[220]Interview with Charles Schultze, February 24, 1988

value society places on clean air, a safe workplace, human life, or viability of future generations.

Public and Individual Decisionmaking--Are the Criteria the Same?

There is also an important difference between public and private decision-making, one that is often ignored by the individualistic microeconomic tradition on which cost benefit analysis is based. To put it simply, our social decisions often are perceived to provide an occasion to display a "respect" for life that is not practiced on an individual level. Privately, we take risks and give life a finite value. There is no reason to believe that these individual risk levels can be summed simply for the purposes of public policy analysis.[221] This distinction is important in understanding the limitations of cost benefit policy analysis in setting social policy. A simple summation of individual preferences denies any sense of a collective social vision of what we want for our neighbors, our children, and even strangers.

Of course, environmental policymaking agencies have in fact monetized human life. The Nuclear Regulatory Commission uses a figure of $1000 per whole body rem, the Environmental Protection Agency in its environmental radiation standards uses $500,000 for each life saved, and the Consumer Production Safety Commission has used figures ranging from $200,000 to $2,000,000 per life.[222] One writer has found a range of $200,000 to $7 million per life used in various regulatory

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[221]Kelman, Ibid.

[222]Baram, MS: "Cost-Benefit Analysis: An Inadequate Basis for Health, Safety, and Environmental Regulatory Decisions," Ecology Law Quarterly, Vol. 8, No. 409, p. 485

endeavors.[223] The truth of the matter is that, in practice, initiation of a cost benefit analysis using such widely-varying figures means that a particular policy has already been approved on grounds other than cost-benefit. One bureaucrat stated that he can remember "...no instance where risk benefit analysis resulted in the conclusion that the agency action should be stopped."[224]

Utilitarianism, Positivism and Cost-Benefit Analysis: Poor Substitutes for Moral Analysis

Cost-benefit analysis is rooted in the philosophy of utilitarianism, which was abandoned by most modern philosophers around the turn of the century.[225] This system of thought can be characterized briefly as maximizing the "greatest happiness for the greatest good." Any action which achieves this is desirable; in short, the ends justify the means. Since cost benefit analysis assumes that society wants to maximize utility through the most efficient allocation of resources, the link between the method and the philosophy is evident.

In its purest (most vulgar?) form, science has strived to eliminate values from an understanding of how the laws of the universe work. The positivist desire to know things with certainty, coupled with the truly remarkable predictive powers science has afforded us, has led many to suppose that science is devoid of values. Clearly, "good" scientists aim to produce work that is unbiased; but this does not mean that science itself does not have values--another case of the fallacy of the assumption that individual characteristics are automatically reflected on a larger

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[223]Greer W: "Value of One Life?" New York Times, June 26, 1985, p. A1, cited in Noble C: Liberalism at Work: The Rise and Fall of OSHA, Temple University Press, Philadelphia, 1986, p. 112

[224]Baram, Ibid., based on interviews with NRC, ERDA, and FEA staffs in Washington DC (Fall 1978)

[225]Ibid. Shrader-Frechette, p. 33-34, 54-57

scale. Scientists receive training that color (and lend meaning to) the "facts" they analyze.[226] Ultimately, it is impossible for science, scientists, or for that matter, any of us, to be free of values. We need them to interpret the world around us. Even the desire to produce unbiased scientific work is a value. If we can agree that values are present in science, and that science is not only a means of uncovering physical laws, then some examples of the things that science values might be problem-solving capacity, simplicity, predictive power, and the concept of "acceptable practice" (the scientific method).

Like science, cost-benefit analysis may also don blinders when it comes to recognition of internal, arbitrary values. For example, cost-benefit analysis implies that values enter only after the calculations of discounted costs or benefits, internal rate of return, etc. and that the values are supplied by the decisionmaker, not the analyst. In truth, value judgments enter every stage of the analysis. For example, the decision to regard something as a cost or a benefit depends on one's values. An economist might tend to automatically regard cheap energy as a benefit, while an environmentalist might see the use of cheaper, but non-renewable, energy resources as a cost. The assessment of unknown scenarios (such as the weight given to plant sabotage in the cost benefit analysis of nuclear power plants), how to assess low probability but catastrophic events (like exposure to mutagens), what discount rate, if any, to use over the long run, whether to compare average or marginal costs, and how to correct market prices for imperfections (e.g. "externalities") are all examples of value-laden decisions that might be made in the course of a cost benefit analysis. Similar types of assumptions are made in a

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[226]Kuhn TS: The Structure of Scientific Revolutions, University of Chicago Press, Chicago, 1962, 1979

quantitative risk assessment. These assumptions show the difficulty in erecting rigid walls between risk management and risk assessment.

These somewhat abstract arguments are useful only if it can be seen that the use of cost-benefit analysis does not preclude struggling with what is right and wrong. In other words, there is ultimately no substitute for a dialogue involving differing value systems in the process of arriving at social decisions. In the environmental arena, it seems likely that an approach where the costs and benefits of different regulatory options are compared to each other using a number of different ethical criteria would be most helpful to the decisionmaker, since all the options would be examined and different choices could not be hidden under the mantle of "reason." In short, efficiency is a means to an end, not an end in its own right.

How should ethics and philosophy be incorporated into scientific pursuits and policy analysis in particular? While a thorough examination of this question lies beyond the scope of this thesis, it is worthwhile to briefly explore some alternatives to the ideal of neutrality. Commonly, it is thought that the only way to be objective is to be neutral, to consider all possibilities as being equally plausible. Some proposed alternatives to this ideal include:

1. Explicit delineation of methodological, ethical, factual, and theoretical assumptions using applied philosophy as one of the disciplines to be incorporated into a policy research team;
2. Use of broader social valuation schemes (other than prices)
3. Use of adversarial proceedings to address disagreements among experts (the science court);

4. Evaluation of alternative philosophical systems, including egalitarianism, classical liberalism, libertarianism, as well as utilitarianism.[227]

While it is difficult to see how these alternatives might be incorporated operationally, the notion of neutrality is particularly seductive. It was Dante who wrote "The hottest places in hell are reserved for those who in times of great moral crisis maintain their neutrality." Another writer says "...perhaps the biggest problem is not how to make (cost benefit analysis) completely neutral, but how to protect ourselves from those who want us to believe (it) can be."[228]

Risk Assessment as a Surrogate for Economic Analysis

How has risk assessment been used for the purposes of economic analysis? An OMB economist recently published a cost-effectiveness evaluation of 44 different safety and health regulations, showing that "many more lives [could be] saved for the same investment or the same number of lives saved for a much smaller investment" if resources were reallocated towards reducing safety hazards and away from health regulations. For example, the cost per life saved from an OSHA standard involving servicing wheel rims was only $500. In contrast, the formaldehyde standard was found to cost $72 billion per life saved.[229] Others have suggested that the use of conservative assumptions in areas where scientific knowledge is uncertain distorts regulation, allowing some possibly low-level risks to be more stringently regulated, while more severe risks are tolerated.[230] Table 3.1

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[227]Shrader-Frechette, Ibid.

[228]Shrader-Frechette, Ibid.

[229]John F. Morall III: "A Review of the Record," Ibid.

[230]Nichols AL and Zeckhauser RJ: "The Perils of Prudence," Regulation, November/December, 1986, p. 13-24

shows how only a few of many possible conservative assumptions tends to multiply the estimated cancer risk.

Table 3.1 Cancer Risk From Various Assumptions

Factor	Range of Possible Reduction In Estimated Cancer Risk
Weight vs. Surface Area	2-12
Maximum likelihood vs. upper 95% confidence limit	2-3
Malignant tumors vs. malignant plus benign tumors	1-2
Average animal sensitivity vs. most sensitive animal	2-5
Pharmacodynamics vs. effective dose	1-6
Risks at shorter than equilibrium buildup time	2-5
Total	15- 10800

Source: Anderson E: "Risk Analysis in Environmental Health With Emphasis on Carcinogenesis," Harvard School of Public Health, 18-20 September, 1984 (Speech), cited in Barnard RC: "Scientific Risk Assessment and the Regulation of Human Cancer Risks: Background and New Directions," American Industrial Hygiene Journal, 48(9), 1987, p. 798-803

The courts and environmental agencies have taken differing positions over the years regarding the applicability of cost benefit analysis to environmental policy. The courts have generally interpreted Section 102(2)(C) of the National Environmental Protection Act (NEPA) to mean that a cost-benefit analysis is required.[231] On the other hand, the primary purpose of OSHA is "to assure as far as possible, safe and healthy working conditions."[232] Feasibility is mentioned in the Act, although it is not clear whether this refers to technical or financial feasibility, or both.

The Supreme Court later said that OSHA must set a standard if a "significant

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[231]Luke JR: "Environmental Impact Assessments for Water Resources," George Washington Law Review, Vol. 45, No. 5, August 1977, p. 1107

[232]OSHA Act, Public Law 91-596, Dec. 29, 1970, Section 2(b)

risk of material health impairment" is found.[233] In Chapter II, we saw that in its Benzene decision, the Supreme Court ruled that any new standard must be preceded by a determination that exposures to chemicals at the existing Permissible Exposure Limit pose a significant risk. But the court stopped short of demanding a cost benefit analysis. In fact, in its cotton dust ruling, the Court specifically rejected the use of cost benefit analysis in setting OSHA standards. Importantly, however, it did reaffirm the need for a risk assessment. As a matter of policy, all environmental government agencies now perform a quantitative risk assessment and some form of cost benefit or economic impact analysis during preliminary rulemaking activity. The latter can be an exhaustive market simulation model[234] or a simple listing of costs and benefits, which is the current practice at OSHA.[235]

The Food and Drug Administration has also not used cost benefit analysis for carcinogens, since the Delaney Clause specifically prohibits any addition of carcinogens to foods, cosmetics, or drugs. However, some attempts have been made to weigh benefits and costs by classifying some carcinogenic substances as either extremely weak or present in such low concentrations that they pose a de minimus risk. Essentially, the idea is that if the risk level is extremely low, then it is a trivial matter with which the courts should not be concerned.[236] Congress voted to

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[233]Industrial Union Department v. American Petroleum Institute, 448 US 607, Appendix A (1980). See also Mintz, Benjamin, OSHA: History, Law and Policy, Bureau of National Affairs, Washington DC, 1984, p. 267-332 (Benzene and Cotton Dust)

[234]See Call, HJ and Massouda NF: "The Methodology and Model Description for the Economic Analysis of the Chlorinated Solvents," Mimeo from the Office of Pesticides and Toxic Substances, Economics and Technology Division, Regulatory Impacts Branch, Environmental Protection Agency, July, 1986.

[235]Interview with Larry Baslow of OSHA's Regulatory Analysis Office, March 2, 1987

[236]Lecos, C: "Cancer, the Law, and Methylene Chloride," FDA Consumer, March 1983, p. 15-17

override the Delaney clause when it permitted the use of saccharin, even though the substance was found to cause cancer in animals. Here, the Court appeared to be extremely prudent, allowing the risk to be passed on to society at large only after specific Congressional action. Thus, the courts are likely to require Congressional action in deciding which risks are unimportant. Ultimately, Congress may need to consider at length how agencies are to treat risk in general, and not just for specific substances.[237] Of course, such action can carry with it important political liabilities or assets. A similar debate is continuing over certain food dyes. On one side, the dye industry argues that the risk posed by these substances is so small as to be essentially meaningless. On the other hand, some consumer groups have argued that since dyes do not really have any intrinsic value (other than to those employed by the dye industry) or social benefit, there is no reason to take the risk, no matter how small. These groups often cite the use of a certain yellow dye used in breakfast cereal. The company involved agreed to remove the dye, and although the appearance of the product was altered, there was no measurable decrease in sales.

So far we have focused on difficulties associated with estimates of costs. However, the use of dyes invokes the question of examination of benefits. Economists generally believe that market mechanisms will most efficiently weed out useless items, since there will be no consumer demand. Regulatory agencies have so far refrained from conducting hearings on the relative benefits of new chemicals, instead focusing on costs associated with workplace and environmental contamination. However, Barry Commoner has posed an interesting question: Why

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[237]Thorne Auchter stressed this point repeatedly during an interview for this thesis.

not require businesses to justify a new product, not solely on projected earnings or other market measures, but on the basis of social utility?[238]

Some risk assessors have begun to ask benefit-related questions in seeking to understand why there is such a large gap between the public's perception of risk and expert's perception of risk.

> If we are more risk averse, are we also more "benefits averse" (i.e. less sensitive to benefits as we become more averse to risks? Do we simply become less interested in new benefits as we become richer? If our perception of risks and benefits has not changed, then how were we able to build an industrial society unless we as a people were more concerned with benefits than with risks?[239]

Others have begun to ask even more fundamental questions regarding the relevance of quantification of probability levels and magnitudes of loss. By focusing only on risks and probabilities, risk analysts have implicitly excluded formal consideration of other factors, such as the benefits gained, voluntariness, equity concerns, public will, etc. They may protest that this is not their job, that consideration of these other factors belongs to the decisionmaker. Compartmentalizing the process in this manner has two effects.

First, it allows the risk analyst to seize the high ground by providing the "rational" part of the analysis. This is similar to the economists' efforts to "rationally" arrive at the most efficient allocation of resources. In both cases, a layman (or a decisionmaker) might well ask, "How can one argue against this?" If the calculated risk is low (or the costs outweigh the benefits), a decision to proceed with tightened regulation automatically becomes "irrational." In short, the weighing of ethics and other intangibles becomes short-circuited and the public is denied a significant role in the decisionmaking process.

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[238]Barry Commoner, Ibid.

[239]Sagan LA: "Beyond Risk Assessment," Risk Analysis, Vol. 7, No. 1, 1987, p. 2

The second effect is an insulation of the expert. The economist or risk assessor need not (indeed, dare not) take positions on the various value judgments necessary to complete a decision. This may explain why so few experts have become public spokesmen. In effect, they abdicate their democratic responsibilities as citizens, choosing not to worry about how their analyses will be used (even though its use has already been ordained by their earlier monopolization of rationality). In both cases, the chances for democratic input by the citizenry is reduced.

This does not mean that economic and risk analyses should be excluded from consideration. Rather, it suggests that the quantitative analysis be mixed with consideration of various intangibles at each step. By making a series of policy decisions on various technical issues, the OSHA cancer policy can best be understood as an attempt to break down the walls between risk management and risk assessment. This may explain some of the controversy surrounding the policy.

Quantitative risk analysis has, in fact, become a separate discipline, with its own journals and norms. While it holds promise, its effect thus far has been to strengthen the economists' hold on environmental regulation. Of course, the public has not been entirely removed from the loop (and ultimately never can be), but when it does act, it is increasingly criticized for making an irrational decision.[240]

The Elements of Risk Assessment

Traditional treatment of the risks posed by environmental hazards have

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[240]The most recent example of this is the controversy surrounding Proposition 65 in California.

traditionally been divided into two categories: Risk Assessment and Risk Management.[241] The first category typically involves the following steps:

1. Evaluation and estimation of exposure and its consequent health effects
2. Hazard identification
3. Exposure assessment, including types, magnitudes, time, duration, number of people exposed, etc. before and after regulation.
4. Dose-response function assessment
5. Risk characterization, with an estimation of the probable incidence rate of the disease(s), and the remaining areas of uncertainty.

In order to minimize the role of values and depict the process of risk assessment as more scientific than risk management, numerous inference guidelines have been developed to explicitly state "...the predetermined choice among the options that arise in inferring human risk from data that are not fully adequate or not drawn directly from human experience."[242] The impact of these assumptions is large for carcinogens when compared to traditional toxicology.

Traditional toxicology asserts that "the dose makes the poison."[243] In other words, there is a certain threshold dose to which most people can be exposed without suffering long term irreversible health effects. This has been found to work quite well for many hazardous substances, such as acids, narcotics, etc.

However, in the case of carcinogens, no one has yet demonstrated what a safe dose is. Instead, a risk function is used to assess the number of excess cancer

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[241]"Risk Assessment and Risk Management of Toxic Substances," Report of the DHHS Committee to Coordinate Environmental and Related Programs, April 1985. See also Risk Assessment in the Federal Government, National Research Council, National Academy Press, Washington DC, 1983, p.3

[242]Risk Assessment in the Federal Government, Ibid. p. 51

[243]Paracelsus (1493-1541 A.D.), cited in Williams, Ibid. p. 9

cases that might be expected at each dose level. In examining uncertainty, it is important to note that there is no consensus in the scientific community concerning the mathematical model to be used in defining the carcinogenic dose-response function, probably due to the complexity of various biological factors, which include:

1. Dose of the toxic agent at the sensitive tissue
2. The nature of the sensitive tissue itself
3. The nature of the tissue's response
4. Rates and sites of biotransformation (metabolism)
5. Toxicity of various metabolites
6. Cumulative nature of the material (persistence in the body)
7. Pharmacokinetic distribution
8. Effect of biological variables such as sex, age, species, strain of test animal, etc.
9. Method of administering dose.[244]

All of our animal testing data and epidemiological evidence result from situations where high doses have occurred among small populations, and then extrapolated into the low dose region to assess the occupational or environmental risk to the nation posed by particular substances. A great deal of controversy continues regarding the most appropriate mathematical model to use for this extrapolation. There are essentially five of them:

1. The linear model assumes that the expected number of chemical-cell interactions is directly related to the dose. This model does not consider the body's ability to repair, detoxify, or metabolize carcinogenic substances.
2. The multi-stage model assumes that the toxic response is characterized by a series of biological events, with each event linearly related to dose.
3. The probit model is based on a typical dose response function.
4. The logit model approaches zero more slowly that the probit model.
5. The Weibull model is a quadratic application of the one-hit theory.[245]

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[244]50 FR 50412-50499, December 10, 1985

[245]50 FR 50412-50499, Dec. 10, 1985

The first two models assume there is no threshold, while the last three assume that there is. Most risk assessment work on hazardous chemicals is now done based on the linear or multi-stage model. The World Health Organization has stated that:

> Use of the linear non-threshold model is recommended for extrapolation of risks from relatively high dose levels, where cancer response can be measured, to relatively low dose levels, which are of concern in environmental protection where such risks are too small to be measured.[246]

Once such an extrapolation has been performed, we need to decide what dose (if any) can be judged to be acceptable. The courts have generally given broad leeway to the regulatory agencies. The Supreme Court has stated that "we recognize that (OSHA's) determination that a particular risk is significant will be based on policy considerations....A reasonable person might well consider a risk of one in a thousand significant, while one in a billion [to be] insignificant."[247] To put these numbers in perspective, Table 3.2 shows risks of death in various industries

Table 3.2 Risks of Death

All Occupations	1.1/10,000
Mining	5.5/10,000
Construction	4.0/10,000
Manufacturing	5.0/100,000

Source: "Accident Facts," National Safety Council, 1983 Edition, John F. Morrall III,
"A Review of the Record," Regulation, November/December, 1986 p.27

Most quantitative risk assessment work currently assumes that a risk of one in a million is insignificant (or socially acceptable). For smaller populations the

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[246]World Health Organization recommendation, cited in 50 FR 50412, Ibid.

[247]AFL-CIO Industrial Union Department v. American Petroleum Institute, 44 US 655, cited in 50 FR 50412, Ibid.

acceptable risk must be higher, since the criterion of one in a million would mean that occupational exposures would have to be drastically reduced, possibly leading to the elimination of a number of industries.[248] In fact, most Permissible Exposure Limits are set, not at the level at which risks become insignificant, but at the level which is financially achievable for the industry.[249] In part, this explains why the standards set by OSHA have generally allowed for permissible exposures that are orders of magnitude higher than those set by the EPA or the FDA. The concept of relative risk involves weighing different risks. For example, the carcinogenic risk of certain chemotherapeutic drugs is usually considered to be less significant than the risk posed by untreated cancer. Thus, the rational person would choose treatment. However, there are wide differences in individual perceptions of quality of life under treatment that could skew this conclusion (i.e., some may choose not to undergo treatment). These are more examples of the difficulty in extrapolating from individual decisions to social policy. Of course, this is not solely a question of technical feasibility. The question of who takes the risks and who gets the benefits is crucial, especially in the occupational setting, where workers historically have had little control over the quality of their workplace environments. Similarly, we are much less tolerant of risks forced on us than we are of risks taken voluntarily.[250] Thus, responsibility for deciding acceptability of risks belongs to all of us. No single institution or discipline can effectively perform a truly complete risk benefit analysis on its own.

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[248]Milvey P: "A General Guideline for Management of Risk from Carcinogens," EPA, in Risk Analysis, vol. 6 No. 1, 1986, p. 70

[249]Interviews with Thorne Auchter and Patrick Tyson, Ibid.

[250]Litai, D, et al.: "The Public Perception of Risk," in Covello VT, et al.: The Analysis of Actual vs. Perceived Risk, Plenum Press, New York, 1983, p. 351-372

Uncertainty and the Irrelevance of Risk Quantification

In fact, it has recently been argued that quantification of risk levels are largely irrelevant, especially when there is substantial uncertainty and when the risks posed by individual carcinogenic substances are quite low. Instead, two risk assessors have argued that "the critical question facing societal risk managers is not 'How safe is safe enough?,' but 'How fair is safe enough?'"[251] These authors go on to show that most people and many policymakers are not concerned with incomprehensible differences in probability levels. Instead, they are concerned with fair process (in which collective consent is acceptable to those who must bear the consequences), with liability-sharing principles, with the magnitude of the adverse consequence, and with institutional credibility; in short, with questions of trust and equity.[252]

Risk Management: Is It Truly Different From Risk Assessment?

Risk management is generally viewed as a more inexact process where values play a larger role in determining the best way of controlling the risk, which can be anything from public education to interdiction. The process is defined as "the integration of risk assessment results with engineering data, social, economic, and political concerns and then weighing the alternatives."[253]

Is it really possible to neatly separate risk assessment from risk management? After the EPA scandal under Burford, William Ruckelshaus, the new administrator, attempted to shore up public confidence in the agency by preaching a strict separation of the two.

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[251]Rayner S and Cantor R: "How Fair is Safe Enough? The Cultural Approach to Societal Technology Choice," Risk Analysis, Vol. 7, No. 1, 1987, p. 3-9

[252]Raynor and Cantor, Ibid.

[253]Raynor and Cantor, Ibid.

> Risk assessment at EPA must be based only on scientific evidence and scientific consensus. Nothing will erode public confidence faster than the suspicion that policy considerations have been allowed to influence the assessment of risk."[254]

Contrast this with a more candid statement, also by Ruckelshaus.

> Risk assessment is...the attempt to quantify the degree of hazard that might result from human activities...Essentially, it is a kind of pretense; to avoid paralysis of protective action that would result from definitive data, we assume that we have greater knowledge than the scientists actually possess and make decisions based on those assumptions."(emphasis added)[255]

One researcher has suggested that political considerations dictated the first statement,[256] while a former OSHA administrator reported that he thought Ruckelshaus had withdrawn the statements entirely.[257]

The Consequences of the Breakdown of the Risk Assessment/Risk Management Typology Breakdown

One other difficulty has emerged with this typology. When a vacuum is created in the risk management phase, the public debate increasingly takes place inside scientific agencies and professional groupings. For example, the National Toxicology Program publishes an annual report listing all known or suspected carcinogens. It has been suggested that these lists are in many respects similar to the 1980 Candidate List which aroused so much controversy in the business community. The NTP list, as well as a similar list published by the International Agency for Research on Cancer, are referenced by the OSHA Hazard Communication Standard. If a substance appears on the list, it becomes regulated automatically.

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[254]Ruckelshaus, quoted in Rushefsky, ME: Making Cancer Policy, State University of New York, Albany, NY, 1986, p. 133

[255]William Ruckelshaus, quoted in Rushefsky, Ibid. p. 173

[256]Rushefsky, p. 150, Ibid.

[257]Interview with Morton Corn, Ibid.

In response to industry pressure, a statement will be added to the introduction of the annual NTP report, stating that the report is only a "hazard identification" document, not a risk assessment.[258] This suggests a further attempt to compartmentalize the decisionmaking process. Are we to have hazard identification, quantitative risk assessment, and risk management? Can we expect this to lead to even further paralysis?

Similar difficulties have surfaced with an OSHA proposal to update its Permissible Exposure Limits with 1987-88 Threshold Limit Values. The latter are set annually by the American Conference of Governmental Industrial Hygienists, a professional society. The new TLVs may also include a statement indicating that they are not intended to be used for regulatory purposes. Some interest groups have argued that the TLVs are set behind closed doors, and are dominated by industry. They say that Congress specifically decided against using such private groups to set standards when it formed the National Institute for Occupational Safety and Health, which is responsible for recommending new exposure limits to OSHA. OSHA has usually not responded to NIOSH's recommendations, possibly due to the absence of risk assessments. The NIOSH recommendations are also considered by many to be unrealistically low. Since NIOSH is housed in the Centers for Disease Control, it sees its mission as much more than simply making recommendations to OSHA--it sees itself as setting the state-of-the-art in occupational health practice in the country.[259] Nevertheless, NIOSH has recently completed its first risk assessment (for radon) and will be sending the recommended exposure limit to the Mine Safety and Health Administration. Unlike

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[258]Personal Communication from Dorothy Canter, Assistant to the Director, NTP, date

[259]Interview with anonymous NIOSH staffer, February 10, 1988

OSHA, MSHA is required to formally respond to the NIOSH recommendation in 60 days. If this process works well, it has important lessons for OSHA-NIOSH relationships.

However the responsibility for risk assessment or risk management is delegated, it should be clear that in practice the two often overlap and that democratic decisionmaking is enhanced when they do. Whether the mechanism is negotiated rulemaking, consensus rulemaking, or public town meetings, the gulf between expert and citizen is reduced. The National Research Council, among others, has suggested that the overlap area be termed "risk assessment policy" to "differentiate the [inference guidelines] from the broader social and economic policy issues that are inherent in risk management decisions. At least some of the controversy surrounding regulatory actions has resulted from a blurring of the distinction between risk assessment policy and risk management policy."[260]

Can Democracy Work?

Of course, none of these data deal with the important concepts of equity, voluntariness, control, delay, or catastrophic potential--all aspects of risk that matter to people. The implication is that risk experts can "tell people what [is] best for them."[261] Increasingly, the public is playing a larger role in risk management decisions that have a direct impact on their lives. Risk and economic analysis can either be viewed as an objective, quantifiable part of any technology or industry, in which case it is likely to form the only basis for policy decision (how can a reasonable person suggest that we spend $17 billion to save a fraction of a life?) or it can be viewed as a way of providing people with useful information to

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[260]Risk Assessment in the Federal Government, Ibid., p. 3

[261]Ottway H: "Experts, Risk Communication, and Democracy," Risk Analysis, Vol. 7, No. 2, 1987, p. 126

be used in political and social discourse.[262] Finding ways to empower individuals to participate in public decisionmaking in an informed manner lies at the heart of a vibrant, technologically-based democracy. Highly technical risk assessments may retard this process in favor of a system thought by experts to be more rational.

That the more democratic process can work was shown by an EPA experiment. Residents in Tacoma, Washington were asked to decide whether a copper smelter, which released large quantities of arsenic (a known carcinogen) into the atmosphere, should be required to install costly pollution control devices which could cause the plant to be shut down, or to permit higher emissions to keep the plant open. In short, the citizens were asked to define what an acceptable risk would be. While the final decision rested with EPA and the courts, all sides involved in the ensuing public debate concluded that the process a positive one. William Ruckelshaus said, "...in all I would call it a qualified success. Those who participated came away with a better understanding of the anatomy of environmental decisions, and local groups were able to come up with technological options that might have increased protection while allowing the plant to remain open."[263]

Conclusion

This chapter shows that consideration of philosophical systems, ethics, political concerns, and scientific evidence enters at each step in both risk assessment and risk management. Therefore, any weighing of alternatives must also include how those alternatives look under different assumptions and value systems. While it is clear that we all take risks, it should also be clear by now that in some cases (exposure to carcinogens perhaps being one of them), the public may choose to

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[262]Ottway, Ibid. p. 128

[263]Kalikow BN: "Environmental Risk: Power to the People," Technology Review, October 1984, p. 55-61

make efforts to control the risk, even if the costs outweigh the benefits involved, and even if the calculated risks are thought to be slight. Firefighters and lifeguards, for example, must respond to all distress calls, even the inefficient false alarms.

How far to control those risks, especially in the face of great uncertainty, cannot be decided by any single bureaucracy, social institution, or stakeholder. An informed, involved, and empowered population is the best guarantee of workable, lasting, and effective regulation of carcinogens.

CHAPTER IV

CASE STUDY:

A COMPARISON OF GENERIC AND SUBSTANCE-SPECIFIC REGULATION OF METHYLENE CHLORIDE

In this chapter, the OSHA carcinogen policy (in its original 1980 formulation, but with elements of quantitative risk assessment added) will be applied to methylene chloride (dichloromethane, or DCM). DCM is currently under consideration at OSHA for specific regulation as a carcinogen. While some of this material is speculative, it should help to clarify the advantages and disadvantages of the generic and substance-specific approaches to regulation of occupational carcinogens. Special emphasis will also be given to the use of quantitative risk assessments using pharmacokinetic models. Final rulemaking hearings have not yet been scheduled, but will probably be highly contentious. DCM enjoys very wide usage, and the economic impact of any proposed regulation will be quite large. In addition, questions of the degree of scientific uncertainty will surface once again, since new technological advances have permitted the use of information regarding how the substance is metabolized. These latter issues are yet another example of how carcinogen regulation remains "on the frontiers of science."

The role of non-regulatory groups is also important in this case. While the current OSHA Permissible Exposure Limit is 500 ppm (as an 8-hour time-weighted average),[264] the American Conference of Governmental Industrial Hygienists has

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[264]The standard also includes a ceiling limit of 1000 ppm, and a maximum peak of exposure limit of 2000 ppm for 5 minutes every 2 hours

issued a Notice of Intended Change for its 1987-88 Threshold Limit Value. The new TLV is to be 50 ppm, 10 times lower than the PEL. The current TLV is 100 ppm.

The Substance-Specific Method

History of Regulation

The current OSHA PEL was derived from a standard developed by the American National Standards Institute (ANSI),[265] which was intended to protect workers from neurological injury from anesthetic-type effects and also from irritant properties. Thus, the OSHA PEL, adopted in 1971, was not intended to protect against cancer. This remained unchanged, even when NIOSH recommended that the limit be reduced to 75 ppm in March 1976,[266] and when the TLV was lowered to 100 ppm in 1975.

In 1980, an animal study showed statistically significant increased rates of salivary gland sarcomas and increases in benign mammary gland tumors in male and female rats exposed to DCM, respectively.[267] Statistically significant increased rates of benign tumors were also found in female hamsters, but no increases in tumors of any kind were found in male hamsters. Several other studies appeared in the following years, but it was not until March of 1985, when the National Toxicology Program reported animal studies showing statistically significant increases

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[265]ANSI Standard Z37.23-1969

[266]"Criteria for a Recommended Standard...Occupational Exposure to Methylene Chloride," NIOSH, DHEW Publication No. 76-138, 1976

[267]Burek J, et al.: "Methylene Chloride: A Two-Year Inhalation Toxicity and Oncogenicity Study in Rats and Hamsters," Toxicology Research Laboratory, Health and Environmental Sciences, USA, Dow Chemical USA, Midland, Michigan. For a review of this study, see "Quantitative Risk Assessment for Occupational Exposures to Methylene Chloride," KS Crump and Company, Inc. October, 1986.

of mammary gland fibroadenomas and malignant neoplasms in the lung and liver,[268] that the regulatory effort began to appear. EPA, CPSC, and FDA initiated risk assessment proceedings to determine if further regulation was needed.[269] In May, 1985, EPA classified methylene chloride as a "probable human carcinogen," instead of the former "possible" designation.[270] CPSC proposed a labelling rule and status update for various household products,[271] and the FDA proposed a ban on the use of DCM in hairsprays.[272]

Characteristically, it required action by an outside group to force OSHA to address the issue. On July 19, 1985, the United Automobile Workers (UAW) petitioned OSHA to publish a hazard alert, issue an emergency temporary standard, and produce a new permanent standard. In response, OSHA refused to grant an Emergency Temporary Standard, but did issue a "Guideline for Controlling Exposure to Methylene Chloride."[273] The document did not establish a legally-enforceable PEL, but did provide a series of recommendations to employers in various industries. It also published an Advance Notice of Proposed Rulemaking on Nov. 24, 1986 to begin the process of developing a permanent standard.[274]

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[268]"Toxicology and Carcinogenesis Studies of Dichloromethane," National Toxicology Program, NIH85-2562, 1985

[269]See 51 FR 42258, Nov. 24, 1986 for a brief review of this history

[270]49 FR 46294, November 26, 1984

[271]51 FR 29778-29809, August 27, 1986

[272]50 FR 51551-51559, December 15, 1985

[273]OSHA Instruction PUB 8-1.2, March 10, 1986, Office of Science and Technology Assessment

[274]51 FR 42257, November 24, 1986, Advance Notice of Proposed Rulemaking for Occupational Exposure to Methylene Chloride

In April, 1986, NIOSH issued a Current Intelligence Bulletin reviewing the results of the NTP study, recommending that exposures be controlled to the lowest feasible level, instead of its former recommendation of 75 ppm.[275]

Currently, the OSHA PEL remains at 500 ppm. Many observe that it is unlikely a final standard will be issued until some time after the elections in November. A final Notice of Proposed Rulemaking is scheduled to be released in March, 1988, but has not yet appeared.[276]

Extent of Exposure

DCM is used in a variety of industries, including aerosols, paint removers, foam blowing, degreasing, electronic, pharmaceutical, and in triacetate fiber and polycarbonate resin production. Annual production is estimated at 265,000 tons, with over 1 million workers potentially exposed. Twenty-six thousand of these workers are thought to be exposed to levels approaching 500 ppm.[277] It is widely used partially because of its relatively low level of flammability.

Quantitative Risk Assessment

It is useful to examine some of the assumptions made in a recent quantitative risk assessment performed for OSHA by an outside contractor. In order to convert the test animal dose to humans, a choice must be made. Should the findings from small rodents be scaled on the basis of weight or surface area? OSHA has typically used weight (with doses expressed in milligrams of agent/kilogram of body

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[275]NIOSH Current Intelligence Bulletin No. 46, "Methylene Chloride," April 18, 1987

[276]"Hazard Communication, Recordkeeping, Z-Table Project Head 1988 OSHA Agenda in Shadow of Election-Year Malaise," Bureau of National Affairs Special Report, January 6, 1988, p. 1240-1252

[277]51 FR 42259-42260, November 24, 1986, Advance Notice of Proposed Rulemaking for Occupational Exposure to Methylene Chloride

weight/day), while EPA has tended to use surface area (with doses expressed in milligrams/square meter/day). If OSHA were to use the surface area method, then the estimated lifetime risk estimate would be roughly 13 times larger using data from mice and 5 to 6 times larger using data from rats.[278] To calculate the dose using the weight method:

$$\text{Dose (mg/kg/day/)} = \text{dose (ppm)} \times 1.2 \times \frac{\text{Molecular Weight of chemical}}{\text{Molecular Weight of air}} \times \text{No. of hours of exposure per day/24} \times \frac{\text{breathing rate} \times \text{days of exposure per week/7}}{\text{body weight}}$$

The formula assumes that 1.2 is the density of air, that the average test rat breathes 0.26 m^3 per day, that 0.4038 kg is the average weight of the rat, that the rat absorbs all of the chemical that is inhaled into the body, and that there is a linear relationship between concentration and dose received. There are other standard values for other test animals, although there are likely to be substantial differences among individual animals within a species. A similar formula is used to extrapolate this dose to an occupational dose for humans. Here, it is assumed that the worker weighs 70 kg, inhales 10 cubic meters of air per 8 hour shift, works 250 8-hour days/year and has a 74-year life span. Other assumptions are required in extrapolating the dose from the relatively high test doses to lower ones where humans are likely to be exposed. However, the doses used in the animal testing for methylene chloride are not that much higher than the PEL.

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[278]Crump KS, "Quantitative Risk Assessment for Occupational Exposures to Methylene Chloride," Ibid. p. 25

OSHA typically uses a computer program, GLOBAL83[279], to generate Maximum Likelihood Estimates (MLE) of risk-related dose. The model employs the multi-stage theory of cancer, and assumes linearity at low doses. The MLE is a standard statistical concept defined as a method of determining the value of a parameter that maximizes the likelihood of the observed data.[280] Ninety-five percent confidence limits are then calculated to provide an upper-bound risk estimate. This is a conservative assumption that usually increases the risk estimate by a factor of 2 or 3. Some economists have proposed the use of the expected value, which is "the weighted average of the risk estimates, with the weight for each alternative equal to the subjective probability that it is correct."[281] These authors do not suggest how "subjective probability" might be quantified. The expected value approach is a sort of compromise between the MLE and the 90% upper confidence limit. In its recent formaldehyde rule, OSHA reported both MLE's and upper confidence limits in justifying a lower PEL.[282]

In a recent DCM quantitative risk assessment performed for OSHA, the extra risk of one in a thousand corresponds to an MLE range of 2.97 to 175 mg/kg/day in test animals. Using the formula given above, the MLE's of risk range from 0.35 to 58 per 1000 workers, assuming 45 years of exposure to the current PEL of 500 ppm. The 95% confidence limits vary from 8.03 to 248 per 1000 workers. Even at the old NIOSH-recommended standard of 75 ppm, the MLEs are between 6.5 x 10^{-3}

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[279]Howe, R: "GLOBAL83: A computer program to extrapolate quantal animal toxicity data to low doses," Prepared for the Office of Carcinogen Standards, OSHA, Contract 41USC252C3

[280]Bhattacharya GK and Johnson RA: Statistical Concepts and Methods, Wiley & Sons, New York, 1977, p. 162

[281]Nichols AL and Zeckhauser, RJ: "The Perils of Prudence," Regulation, November/December, 1986, p.21

[282]52 FR 46220, December 4, 1987

and 9.0 per 1000 workers, with upper confidence limits between 1.21 and 41.9 per 1000 workers.[283] This is several orders of magnitude higher than the socially-acceptable risk level of one in a million identified in earlier chapters, even using the MLEs. In this case, the debate over whether to use MLE's, expected values, or upper confidence limits would appear to be moot, since they are all well above 1 in a million. These estimates were derived from animal studies that, for once, were not substantially greater than occupational exposure levels. Animals were tested at concentrations of 0, 1000, 2000, and 4000 ppm in the NTP study.

The risk assessment also examined epidemiological studies. Friedlander found decreased levels of malignant neoplasms among workers exposed to DCM. Forty-one malignancies were found among a group of exposed workers, while 58 were expected. Thirteen lung cancers were found while 21 were expected, and 14 digestive system neoplasms were detected whereas 17 were expected. In short, exposed workers had lower rates of cancer at these sites than did the control group. However, 8 pancreatic cancers were found, while only 3.2 were expected. Personal air sampling data are available for this group of workers. Generally, exposures were far below the PEL, ranging from an average of 20 ppm to 140 ppm, depending on job category.[284]

Even though the total malignancies were lower than expected (except for pancreatic cancer), the risk assessment concluded that:

> the epidemiological data can not rule out the possibility that methylene chloride is a human carcinogen. This point is illustrated by the [statistical] power of the studies...it is highly likely that any true

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[283]Crump, Ibid. p. 20

[284]Friedlander, B, et al. "1964 Methylene Chloride Cohort Mortality Study. Update through 1984." Unpublished report for Eastman Kodak Company, Rochester, NY, cited in Crump, Ibid.

carcinogenic effect that is manifested in the liver or pancreas, for example, has been missed.[285]

The power to detect an increased relative risk of 2.5 is only 0.26. The study concludes that the epidemiological evidence is therefore consistent with the animal evidence, in the sense that it does not contradict the calculated risk levels from animal studies. Because of the small population involved, the epidemiological studies are not useful in either supporting or denying they hypothesis that DCM is a human carcinogen.

Generic Regulation of Methylene Chloride

With this information as background, how would the generic OSHA carcinogen policy have affected the regulation of methylene chloride? First, it seems likely that the first animal study reported in 1980, together with earlier studies showing mutagenic activity in bacteria,[286,287,288] would have provided sufficient evidence to place methylene chloride on a Priority or Candidate List. DCM did not appear on the initial Candidate list published in August, 1980,[289] but would appear to meet the definition of a "potential occupational carcinogen" in the 1980 cancer policy, which is defined as "...any substance...which causes an increased incidence of benign

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[285]This material is based on Crump, Ibid.

[286]Kirwin CJ and Thomas WC: "In vitro microbiological mutagenicity studies of hydrocarbon propellants," Journal of the Society of Cosmetic Chemistry, Vol. 31, p. 367-370, 1980

[287]Jongen, WMF, et al.: "Mutagenic Effect of Dichloromethane on Salmonella typhimurium, Mut Res, Vol. 56, p. 245-248, 1978

[288]Simmon VF, et al.: "Mutagenic activity of chemicals identified in drinking water," in: Scott D, et al., eds, Progress in Genetic Toxicology, Elsevier, Amsterdam, p. 249-258, 1977

[289]45 FR 53672, August 10, 1980

and/or malignant neoplasms...in...one or more experimental mammalian species..."[290] Importantly, placement of DCM on the list would not have been "subject to judicial review or be the basis for any legal action...[since] inclusion...does not reflect a final scientific determination..."[291]

Next, OSHA would have determined whether DCM should be classified as a Category I or Category II carcinogen. Since there was evidence in both animals and short-term bacterial mutagenicity tests, it seems likely that it would have been designated as a Category I carcinogen. Section 1990.112 (a) of the OSHA carcinogen policy states that "A substance shall be identified, classified and regulated as a Category I Potential Carcinogen if, upon scientific evaluation, the Secretary determines that the substance meets the definition of a potential occupational carcinogen in...a single mammalian species in a long-term bioassay where the results are in concordance with some other scientifically evaluated evidence..."[292] In this case, the mutagenicity testing would have fulfilled the concordance requirement. NIOSH also supported the classification of DCM as a Category I carcinogen in its Current Intelligence Bulletin No. 46: "These data...are sufficient to classify methylene chloride as an OSHA Category I potential carcinogen...." NIOSH goes on to state that supporting epidemiological studies are not required by the carcinogen policy and that exposures should be reduced to the lowest feasible limit.[293]

Where would DCM have been placed in terms of agency priority? This would have been a function of a number of factors, including severity of exposure, number

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[290]45 FR 5283, January 22, 1980

[291]45 FR 5285, section 1990.131

[292]45 FR 5284, January 22, 1980

[293]NIOSH Current Intelligence Bulletin No. 46, April 18, 1986

of workers exposed, and technological and economic feasibility. Hooper and Gold have introduced the concept of an Exposure Potency Index (EPI) to aid in this process.[294] Briefly, the EPI is the percentage of the dose in humans which caused cancer in test animals. It can be calculated by dividing the PEL by the dose required to induce tumors in animals. Thus:

$$EPI = \frac{\text{PEL (mg/kg/day)}}{\text{Cancer Effective Dose}}$$

The Cancer Effective Dose can be defined as:

$$CED = \frac{\text{Test Exposure in mg/m}^3 \text{ x (inhalation m}^3\text{/day)}}{\text{body weight of test animal(mg)}}$$

These authors have calculated the EPI for a number of industrial chemicals, including DCM. Their results are shown in Table 4.1.

Table 4.1 Exposure Potency Indices for Selected Chemicals

Chemical	EPI (%)
1,3-Butadiene	36
Formaldehyde (old PEL - 3ppm)	28
Tetrachloroethylene	7.8
Trichloroethylene	3.2
Propylene Oxide	2.2
1,2 Dibromomethane	1.5
Ethylene Oxide	0.8
1,2-Dibromo-3-chloropropane	0.2
Dichloromethane (methylene chloride)	2.8

Source: Adapted from Hooper K and Gold LS: "Ranking the Carcinogenic Hazards of Occupational Exposures: Exposure-Potency Index Values for Nine Volatile Industrial Chemicals," in Sorsa S and Norppa H, eds: Monitoring of Occupational Genotoxicants, Liss, New York, 1986, p. 223

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[294]Hooper K and Gold LS: "Ranking the Carcinogenic Hazards of Occupational Exposures: Exposure-Potency Index Values for Nine Volatile Industrial Chemicals," in Sorsa S and Norppa H, eds: Monitoring of Occupational Genotoxicants, Liss, New York, 1986, p. 223

This means that at the current PEL, workers receive 2.8% of the dose required to cause cancer in 50% of the test animals for methylene chloride. If these data are multiplied by the number of workers exposed, then a rational priority-setting scheme can be approximated by calculating an EPI Severity Rate, defined as the product of the EPI (in percent) times the number of workers exposed. These results are shown in Table 4.2.

Table 4.2 EPI-Severity Index for Some Volatile Chemicals

Chemical	EPI(%)	No. of Exposed Workers	EPI Severity Rate
1,3-Butadiene	36	60,000	21,600
Formaldehyde	28	516,000	144,000
Tetrachloroethylene	7.8	577,100	45,000
Trichloroethylene	3.2	518,000	16,600
Propylene Oxide	2.2	39,400	867
1,2-Dibromomethane	1.5	6,300	95
Ethylene Oxide	0.8	96,000	768
DBCP	0.2	350	0.07
DCM	2.8	850,000	23,800

Source: Hooper and Gold Ibid. and NIOSH. Part-time and full-time workers have been combined.

The new OSHA formaldehyde rule has reduced the PEL from 3 ppm to 1 ppm (8-hour time-weighted average), so the EPI Severity Rate would be about one-third the value shown in Table 4.2, using current values. Of course, this type of analysis ignores economic feasibility considerations, and the carcinogen policy warns against the establishment of a "rigid formula...to assign predetermined weight to each factor." But it should be clear that at least among this group of carcinogens, DCM is one of the more important carcinogens to be regulated.

Assuming that DCM would have been placed on the Priority List, and that OSHA would have initiated a study concerning the economic and/or technological

feasibility of reducing exposures, the Advance Notice of Proposed Rulemaking (ANPR) would have been issued in 30 days. The ANPR would have had a comment period of no more than 30 days. At this point, a Notice of Proposed Rulemaking (NPR), followed by a comment period of a maximum of 60 days, would have been published in the Federal Register. The carcinogen policy stated that the hearings would begin no later than 100 days after the ANPR, so the total rulemaking period would have been:

Priority List Development	180 days
ANPR	30 days
Comment Period	30 days
NPR Comment Period	60 days
Rulemaking Hearings	100 days
Post Hearing Comment Period	90 days
Final Standard	120 days
Total	610 days

Thus, from the time animal and/or human data first became available, less than 2 years would have been required to establish a final rule, based on the model standards contained in the policy. If substitutes were available for certain processes, then the alternate technology would have been developed more rapidly, since DCM would have been banned ("no" exposure would have been permitted). For example, paint stripping can be performed using DCM, bead blasting, or lasers. Even though the capability exists, lasers and bead blasting have not been implemented on a wide scale, although some observers believe these applications will now be accelerated under the threat of tightened regulation. Even if substitutes were not available, the PEL would have been dramatically reduced to a level as low as feasible.

If the animal data that first appeared in 1980 were of sufficient quality, then a final rule would have been on the books by the end of 1982. Even if such a ruling could not have been made until the appearance of the NTP studies in 1985,

the rule would have been in place by 1987. Presently, OSHA has not yet issued the Notice of Proposed Rulemaking, and hearings have not even been scheduled.

Using the results of the quantitative risk assessment MLE's described above, we can calculate how many cancers might have been avoided had a generic policy been in place and enforced. Recall that the MLE's varied between 0.38 - 58 per 1000 workers and that the 95% confidence limits varied between 8.03 - 248 per 1000 workers. If we assume that the risk declines in a linear fashion for those with lower exposures, and that exposures below the PEL are evenly distributed for all 1 million workers potentially exposed, then we can calculate average 95% confidence limits for the entire range of exposures:

	Risk/1000 Workers	
Exposure(ppm)	95% confidence (lower)	(upper)
500	8.03	248
400	6.42	198
300	4.82	149
200	3.21	99
100	1.61	50
1	0.016	0.5
Average	4.02	124

Thus, the 95% average confidence limits for exposures between 1 ppm and 500 ppm are 4.02/1000 workers and 124/1000 workers. Since this does not include workers with exposures greater than 500 ppm, the true risk may be underestimated. On the other hand, it is likely that many more workers have exposures below 100 ppm, and that the exposure distribution is not linear. An OSHA contractor estimated

that the average 8 hour time-weighted average exposure was 22.4 ppm for industry.[295] Thus, the assumption presented above may overestimate the true risk.

If we then assume that it takes five more years to issue a final DCM rule under the current "muddling through" substance-specific method of regulation, and that a rule could have been issued as early as 1983, then there would a delay of roughly 10 years that could have been avoided had a generic carcinogen policy been in place. Since the confidence limits are lifetime risk estimates, we can estimate the number of cancers that may have been avoided during those 10 years, assuming an average lifespan of 74 years, and a total exposed worker population of 1 million:

$$\frac{4.04/1000 \times 10 \times 1{,}000{,}000}{74} = 546$$

$$\frac{124/1000 \times 10 \times 1{,}000{,}000}{74} = 17{,}000$$

Thus, between 546 and 17,000 cancers caused by exposure to this single substance could have been avoided had a generic cancer policy been in force, using conservative assumptions (i.e., 95% confidence limits). If less conservative assumptions (e.g., MLE's) had been used, the figure would have been reduced to between 181 and 5,700 cancers. If the average exposure (22.4 ppm) had been used, the number of cancers prevented would be between 49 and 1,500.

Pharmacokinetics

DCM has been the focus of extensive research examining how it is metabolized in the body. Would the carcinogen policy have permitted a reexamination of its final standard on the basis of this new evidence? This is an important question,

[295]Pedco Environmental Report, cited in 51 FR 42257, Nov. 24, 1986 (Advance Notice of Proposed Rulemaking for Occupational Exposure to Methylene Chloride)

since some critics argued that the policy would be inflexible, and would "freeze science."

For many years it was thought that DCM was converted into carbon monoxide, explaining its acute toxicity (central nervous system depression). This biotransformation occurs through a metabolic mechanism known as the P-450 mixed function oxidase (MFO) pathway, which takes place primarily in the liver, and, to a lesser extent, in the lung. However, formic acid was detected in the urine of workers exposed to DCM, suggesting that another pathway exists. Working through glutathione-S-transferase (GST), an enzyme found in a different part of the liver, and also to a lesser extent in the lung, the possibility that DCM could be also metabolized to carbon dioxide, with formaldehyde and formic acid as intermediates, was stipulated.[296]

The two pathways may work at different rates for different exposure levels. Some researchers have stated that this explains why there is a carcinogenic effect in mice at low dose levels, while there is no cancer in rats or other species. (Mice have a higher rate of GST metabolism.) The MFO pathway can be saturated, while the GST pathway cannot (i.e. it operates through first order kinetics). Both pathways are thought to produce substances capable of interacting with macromolecules like DNA, resulting in carcinogenesis. The reason that mice had higher rates of cancer than did rats or hamsters in the NTP study is because the GST pathway is capable of producing more of the toxic intermediate than the MFO pathway at high doses (in theory). Mice have markedly higher rates of GST

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[296]See Reitz RH and Andersen ME: "Physiologically-Based Pharmacokinetics and the Risk Assessment Process for Methylene Chloride," Dow Chemical Company and US Air Force, AFAMRL/THB, Wright-Patterson Air Force Base, July 15, 1985 and EPA: "Update to the Health Assessment Document and Addendum for Dichloromethane: Pharmacokinetics, Mechanism of Action and Epidemiology" (Draft), EPA/600/8-87/030A, Washington, July, 1987. See Crump, Ibid. for a review

metabolism, followed by rats, hamsters, and humans (based on in vitro testing of tissue samples), respectively. Since mice are already predisposed to liver cancer, then the tests dramatically overestimate the cancer rates actually experienced by humans, according to this theory.[297] In addition, this may mean that dose-response curves cannot be considered to be linear, since there are different rate constants for the two pathways.

However, there are important assumptions here. The mechanistic models do not rule out the possibility that DCM itself, not its metabolites, causes cancer. The concentrations of MFO intermediates also does not explain the tumor incidence in the mouse lung and liver and the observed difference in mice and hamsters. Finally, the sensitivity of the pharmacokinetic model has not been evaluated for various parameters, such as individual animal differences, and the uncertainty in the model has not been quantified. Nevertheless, most observers seem to feel that the use of pharmacokinetic data is a major advance in the practice of risk assessment,[298] since a plausible mechanism for tumor formation can be proposed and perhaps one day fully validated.

The relevant question here is whether this advance in science should mean that the regulation should be delayed until some of these questions can be resolved, or if such certainty is not required to take protective action. The cancer policy is quite clear on the issue of metabolic differences:

> Arguments that differences in metabolic profiles can be used to demonstrate that a chemical found positive in an experimental study in a mammalian system would pose no potential carcinogenic risk to exposed workers will be

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[297]European Chemical Industry Ecology and Toxicology Centre: "ECETOC Statement No. 4 - June 1987: Current Results from European Chemical Industry-Sponsored Research into Species Differences in the Toxicology of Methylene Chloride," OSHA Docket Document 10-36

[298]Crump, Ibid. p. 83

> considered by the Secretary only if the evidence presented for the specific substance...meets the following criteria:
> i. A complete metabolic profile, including identities of trace metabolites, is presented for the experimental animal species.
> ii. A complete metabolic profile, including identities of trace metabolites, is available for a human population group representative of those who are occupationally exposed.
> iii. Documented evidence is provided for ascribing the carcinogenic activity of the substance in test animal species to metabolites produced only in that species and not in humans; and
> iv. Documented evidence is provided to show that other metabolites produced also in humans have been adequately tested...[299]

Since both metabolic pathways have been detected in humans, it would appear that section iii would rule out the use of this data, at least for now. In fact, the EPA has arrived at the same conclusion:

> In view of the uncertainties involved, the changes in DCM's carcinogenic potency that result from different uses of the available pharmacokinetic information are not, in practical terms, very distinct. Discussion of the issues has been worthwhile because of their theoretical importance rather than their practical significance in the present case.[300]

Thus, instead of "freezing science," the policy would facilitate the generation of additional useful scientific information to meet the requirements of the cancer policy. Paragraph iii above would have helped to ensure that the research was structured to provide the greatest degree of certainty possible. Instead of requiring a standard of scientific certainty that DCM causes cancer, the policy requires some level of scientific certainty that DCM does not cause cancer, especially when there is evidence to the contrary. This basic concept of presumptive rebuttal is crucial, and we shall examine it further in the final chapter.

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[299]45 FR 5287, section 1990.144(c), OSHA Cancer Policy

[300]EPA: "Update to the Health Assessment Document and Addendum for Dichloromethane (Methylene Chloride): Pharmacokinetics, Mechanism of Action, and Epidemiology," EPA/600/8-87/030A Review Draft, Washington, July 1987, p. 111

CHAPTER V

CONCLUSIONS

The Major Findings

1. A generic cancer policy at OSHA is considered to be a necessity by all the major players involved, with the exception of economists, who prefer to analyze the impacts of each chemical regulated.
2. Economists, risk analysts, and industrialists all have a stake in making that policy conform to the guideline type of carcinogen policy. Conversely, workers have an interest in making the policy a legally-enforceable one. While scientists may not have a stake professionally, they would probably be more at ease with the guideline approach, since this would limit the extent of outside influence on their research.
3. Risk assessment and risk management cannot be neatly separated into compartments, one scientific, the other value-laden. In practice, the two mix. The product is a policy shaped by uncertain scientific knowledge and the social values of the dominant political forces. Democracy is enhanced when risk management issues are mixed openly with risk assessment issues.
4. Economists, with support from risk assessors, have gained hegemony in the field of cancer risk regulation by focusing on limited resources and calling for "hard choices" and "rational decisions." This means that society will continue to struggle with ethical dilemmas. Unless issues like equity, public participation, and fairness are raised openly, the nation is likely to become more undemocratic, relying on experts and serving dominant industry interests.

5. The presumptive-rebuttal approach, currently limited to screening programs, should be extended to standards-setting programs like OSHA. The OSHA cancer policy is one way to do that.
6. Organized labor has been conspicuously absent from the effort to develop and implement a generic cancer policy. The policy is at once complex and diffuse. This may help explain why it has received such low priority in this decade.
7. The cancer policy should be seen as an attempt to provide usable information to the public, and to allow the public to have action taken on uncertain scientific information through formal principles. An informed public is essential to a vibrant democracy. If we truly value public participation in decision-making, we must have a generic cancer policy. The record shows that the approach is feasible, but we have not yet mustered the will to implement it.

The Necessity of a Generic Cancer Policy

Is a generic cancer policy needed at OSHA? All the major decisionmakers interviewed for this study indicated that there is little alternative in the face of the large number of chemicals in use. The current pace of rulemaking activity is too slow to allow the agency to fulfill its mandate. In short, there appears to be strong support for a "comprehensive rational" cancer policy and general discontent with the "muddling through" approach, even though the latter more closely defines the historical experience. This discontent is evident across the political spectrum, from the activist outlook personified by Eula Bingham, to the more cautious anti-regulatory stance of Thorne Auchter and some economists.

The more difficult questions concern whether such a policy is feasible. There are substantial disagreements over the policy's proposed scope and content. Economists argue that since different chemicals occupy different positions in the economy, the economic impact of regulating chemical substances must be assessed

individually. Similarly, risk assessors are reluctant to adopt simplistic models to speed up the risk assessment process, since risk estimates may become even less accurate or plausible than they are now. Risk assessment is seen as a new discipline which requires extensive flexibility not amenable to standardization.[301] The increase in toxicological understanding may also militate against a generic approach. For dichloromethane, we saw that the increased use of pharmacokinetic data may require a more specific understanding of metabolic pathways. Scientists may tend to support the "guideline" approach specified recently by the EPA and OSTP, which may enable policy to keep pace better with current knowledge. At the same time, it may have less impact on commercial dissemination of carcinogens, since the guidelines are not legally-enforceable standards, and do not have the rulemaking deadlines contained in the 1980 OSHA policy. At least one policy analyst also views the 1980 OSHA policy as "extreme" and rigid.[302] Thus, scientists (trained to accept only near-certain evidence as meaningful), economists (trained to accept utilitarianism), and at least some policy analysts (trained to present a balanced perspective) all have some stake in the guideline approach. If true, it would not be surprising to see a new OSHA cancer policy closely resemble the current EPA and OSTP guidelines.

In Chapter II, we saw how some risk estimates have declined in this decade. Whether this is due to risk-tolerant assumptions of the Reagan administration, or the product of new scientific knowledge is difficult to determine. It seems likely

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[301]Hattis D: "What's Wrong with Quantitative Risk Assessment?" Paper presented at the Conference on Moral Issues and Public Policy Issues in the Use of the Method of Quantitative Risk Assessment, Georgia State University, September 26-27, 1985. Author is with the Massachusetts Institute of Technology Center for Policy Alternatives.

[302]Rushefsky, Ibid. p. 90

that both processes proceed at once--that the "scientific" risk assessment process mixes with the "political" risk management process.

There is troubling evidence that certain assumptions may not have been conservative enough. Recent reports of loss of stratospheric ozone, together with the well-known "greenhouse" effect suggest that the environment may not be self-cleansing, as the economists have assumed. And although there are numerous alternative explanations as to why the cancer incidence rate is climbing, there should continue to be concern about whether we are indeed acting quickly enough. Under this second scenario, the gap between a scientific approach (i.e., one requiring nearly-absolute proof) and a prudent one is pressing.

Are we being sufficiently prudent? Short of the appearance of catastrophe (i.e., an indisputable cancer epidemic or obvious mutations), there is likely to be a lack of consensus on this among the scientific community for the forseeable future. Policy actions will thus continue to be formed by a mixture of the prevailing political climate and current scientific knowledge. Thus, "...science and policy mix: the scientist is a policy entrepreneur, science poses problems, politics uses science to justify policy actions or policy changes, scientific research receives public funding, and regulatory science comes into being."[303] An increasingly knowledgeable electorate is likely to demand a larger role in decisionmaking in this area.

The choice of assumptions rests in large measure on how risks and benefits are perceived. This is not simply a balancing of cost and benefits, or ranking of priorities, but an important social decision that indicates a consensus on the nature of our limitations. Economists have argued forcefully that our resources, which include both material goods as well as time and energy, are limited, and that

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[303]Rushefsky, Ibid.

society needs to rationally choose the mix of goods and services that maximize human welfare. They state that greater attention needs to be given to opportunity costs and "hard choices." Risk assessors have attempted to help make those choices through various ranking schemes indicating relative risk, implicitly placing bounds on what a rational decision should look like, and perhaps inadvertently preventing other, more intangible but important considerations from entering the picture.

Once we accept the assumption that our resources are in fact limited, then we face a number of insoluble ethical dilemmas. For example, recent developments in epidemiology and advances in exposure assessments have resulted in clearer identification of specific populations at increased risk. The ethical responsibility to inform those at risk is embodied in a current bill before Congress[304] and in the large number of right-to-know regulations that have swept the country. What seems like a very low-level risk which should be accepted by rational individuals may well become unacceptable once individuals are identified. With a worldview of limited resources, then, some workers will face increased risk so that the rest of society will benefit from the products of their labor.

Under the assumption that resources are limited, we are left with ethical choices that are impossible to make, and ultimately lead to paralysis. Do we allow some estimated number of workers to contract cancer to provide goods to the rest of us? One writer has suggested that America is in the grip of an "epidemic of nosophobia, literally defined as a morbid fear of illness,"[305] and that such fear is an irrational failure to appreciate the benefits of chemicals in the modern world. Yet if it is true that increased affluence brings with it a lower appreciation for

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[304]"High Risk Occupational Disease Notification and Prevention Act," HR 162 in the House and S 79 in the Senate, sponsored by Gaydos and Metzembaum, respectively.

[305]Whelan EM: "America is in the grip of a new epidemic: the morbid fear of illness," Atlanta Journal Constitution, October 23, 1987, p. A-23

additional benefits at the margin, then such a fear may not be irrational at all. It simply means that society may not wish to continue to achieve further growth, which economists usually take to mean increased goods and services. It suggests that society wishes to move in new directions, with important consequences for how we define needs and wants, and how we choose to perform work. Such a transition would be a wrenching experience for a market-based, growth-oriented economy; there is admittedly little evidence of such a trend. Slow-growth advocates remain small in number and without authority.

Does it make sense to say that some resources are unlimited? Before the question is dismissed out of hand, it is important to understand that even economists recognize the presence of "intangibles." Creativity, love, visions of the future--all of these are resources (not merely concepts) that few of us would wish to limit. If we make choices based solely only on what our tangible capabilities are, then we may lose important abilities to choose directions and make decisions which are morally sound. In short, we simply aim for what is achievable and economically profitable, not what is perceived as being worthwhile or right or just. Some elements of goals are always beyond reach, and if we simply allocate resources to the mix of activities which is most likely to increase economic wealth, we lose direction, and fail to determine whether additional growth is in our best interest.

Consider again a quote from C. V. Cox, a representative of the Chemical Manufacturer's Association: "As we all know, utopias do not exist, and energies spent trying to reach an unrealistic goal <u>are spent in vain</u>...We should strive to reduce risks to a level that reaches toward zero, but any attempt to actually try to reach absolute zero <u>will mean misspent resources</u>."[306] In essence, he has denied

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[306]Cox, CV: "Risk is Normal to Life Itself," Ibid.

the power of vision as a guide to social action. It does not require a significant leap to recognize that a generic cancer policy such as OSHA's could be characterized as a utopian policy that is simply not possible. This is why the AIHC compared the policy to the "unrealistic" Delaney clause. But the essential point of both Delaney and the OSHA cancer policy is to provide a direction for action, and a plan for how to get there. What does this concept of certain unlimited resources mean for the development of generic regulation of carcinogens? Essentially, it provides a way out of some of the ethical dilemmas described earlier. It means that efforts to identify, classify and regulate carcinogens in the workplace are worthwhile activities that should be supported, even if it is true that the relative risks are slight when compared to other risks. It suggests that the danger of regulating a non-carcinogen as a carcinogen is less important than the failure to regulate. Most importantly, it suggests that the embryonic environmental ethic, which requires not continued growth, but a continuous desire for improvements in health and safety, cannot be dismissed as an irrational aberration of modern society fomented by the media. Work then becomes not only a means to produce, but a way of improving the human condition through means other than supply of commodities. A fundamentally new definition of needs and wants is indicated.

If the slow-growth ethic eventually comes to dominate the high-growth ethic in modern society, then the presumption-rebuttal approach codified in the OSHA cancer policy would become more acceptable than it is presently. Of course, business interests have a large stake in continued growth, and a presumption-rebuttal approach is obviously a direct threat. This new approach is finding increased expression, however. The OSHA Hazard Communication Standard has elements of the presumption rebuttal approach. Employers are required to report evidence of carcinogenicity of products on Material Safety Data Sheets. They can

also rebut such findings by citing other negative studies, but the standard contains language indicating that a single well-conducted animal study showing carcinogenicity is sufficient cause to provide warning. Thus, the standard incorporates prudence as the dominant feature. Presumptive rebuttal was also included in a proposed state law in Ohio, although it was never adopted as law.[307] The Toxic Substances Control Act, if enforced to the letter, would require extensive testing of all new chemicals. In short, new chemicals would need to be proven safe. In practice, the burden of proof currently rests with those trying to prove the presence of a hazard. Increased affluence may mean that we can now afford to shift those assumptions. The OSHA cancer policy should be seen as an attempt to extend presumption-rebuttal from screening programs (such as the Toxic Substances Control Administration) to standards-setting programs like OSHA. The initial effort suffered a set-back, but the need is still present.

The results of the interviews conducted for this thesis also indicate the need for several new institutional arrangements. The absence of a working relationship between OSHA and NIOSH has harmed both agencies. OSHA has generally not responded to NIOSH recommendations for new standards, resulting in extensive litigation and agenda-setting by outsiders. In turn, NIOSH has increasingly seen its standard-recommending function as secondary to defining the current state-of-the-art in occupational medicine and epidemiology. While this is important, the overall result has been lower budgets for NIOSH, and a sense that NIOSH is largely

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[307]"Law Proposed by Initiative Petition first to be Submitted to the General Assembly [of Ohio] to enact sections 3710.99...to inform and protect workers exposed to toxic substances in the workplace," October 16, 1980. Section 4123.681 says in part,"Where an employee...sustains an occupational disease...from exposure to toxic substances known to produce such disease, there shall be a rebuttable presumption that such occupational disease...is a result of the employment."

irrelevant to the standards-setting process. The present $60 million dollar budget for NIOSH is smaller than individual grants offered by other scientific agencies.

A more effective NIOSH would give OSHA some measure of insulation from litigation. Upon receiving petitions, OSHA could argue convincingly that it is following recommendations from NIOSH, which had been decided upon for a number of publicly-stated reasons. This is not to suggest that petitioners be prevented from due process; it merely means that OSHA could exercise a greater measure of control over its own agenda. A more effective OSHA would respond formally to NIOSH recommendations within a specified time period, forcing NIOSH to make recommendations that are more likely to be acted upon. In fact, such an experiment is now underway. NIOSH has recently completed its first risk assessment (regarding exposure to radon). A proposed standard and the risk assessment were delivered to the Mine Safety and Health Agency (MSHA), which is now formally required to respond to the NIOSH recommendation in 60 days. If successful, this exercise has important lessons for NIOSH-OSHA relationships.

Better communication could also lessen OSHA's dependency on expertise from outside consultants. The prospect for increased citizen participation is also enhanced, since reliance on "consensus" standards (such as TLVs, which are more likely to be set without public participation) is reduced.

An active OSHA carcinogen policy also has important implications for the National Toxicology Program. Current business-led efforts to downgrade the NTP's work as "hazard identification documents" (as opposed to "risk assessments") may ultimately impede the important work of the scientific agency. Public debate over proposed classification of carcinogens rightfully belongs in the rulemaking arena, not in a scientific arena, where involvement of citizens is more likely to be restricted due to the technical nature of the issues. The citing of the NTP list and

IARC lists in other regulations transfers the debate from a political arena to one which is more technical, and hence less accessible. Such accessibility is important to the democratic process. Of course, the scientific programs like NTP will never be the idealized "pure" scientific agency, completely aloof from the political winds.

The relationship between OMB and OSHA needs to be better defined. Carcinogen risk assessment guidelines by the two agencies differ extensively. Congress should address at length how society wishes to address uncertain health risks, and which risks society regards as acceptable (perhaps by some combination of magnitude, fairness, formal consideration of benefits gained from taking the risk, equity, compensation, voluntariness, and perhaps probability). Similarly, Congress needs to consider possible limitations on the scope of judicial review of agency standards. If those standards are the result of democratic rulemaking processes which are in accordance with the requirements of the Administrative Procedures Act, there may be little useful role for further judicial review. The cynical use of judicial review as a delaying tactic has to be restrained if we are to make progress. While it is clear the courts are best equipped to rule on matters of process, it is far from evident that judges possess the abilities to rule on matters of substance. The costs involved in delay are substantial in terms of lives lost, as the DCM case study illustrated. The OSHA cancer policy provides for substantial public input, and has never been accused of violating the APA. While this has most probably been due to the failure to fully implement the policy, Congress may wish to limit the courts' ability to hear cases which counter the agency's actual findings.

On one other point, all decisionmakers interviewed for this study agreed: Carcinogen regulation is an enormously complicated process, fraught with difficulties and uncertainties. Yet the case study of DCM showed the clear and present need

for such a policy. Expedited rulemaking on this single substance alone would probably save lives; this alone should be sufficient to make it worth doing.

This story of the OSHA cancer policy would not be complete if we did not consider the role of another important actor. Organized labor has, for the most part, been conspicuously absent from the development of the policy. Their efforts have been limited to offering testimony during the hearings.[308] Instead, unions have chosen to wage a series of court battles over specific substances, such as formaldehyde, benzene, and ethylene oxide. One possible explanation for this is that unions have only recently begun to employ limited numbers of health and safety professionals, and may have lacked the expertise to participate significantly in the debate. Table 5.1 shows the number of such professionals employed by organized labor.

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[308]Interview with Franklin Mirer, United Automobile Workers Director of Health and Safety, American Industrial Hygiene Conference, San Fransisco, California, May 16, 1988

Table 5.1 Union Health and Safety Staff in 14 Selected High Hazard Unions

Category	1976	1983
Doctors	5	3
Industrial Hygienists	8	15
Lawyers	5	8
Engineers	5	4
Epidemiologists	1	2
Public Health Professionals	5	3
Economists	4	2
Occupational Safety & Health Specialists	0	4
Occupational Safety & Health Coordinators	0	16
Nurses	0	1
Legislative Representatives	0	1
Educators	0	1
Others	0	10
Chemists	2	0
Total	35	70
Full-time	20	44

Source: 1983 Survey of Fourteen Unions Occupational Safety and Health Programs, Public Citizen Health Research Group, Washington, DC, 1984, cited in Noble C: Liberalism at Work, the Rise and Fall of OSHA, Temple University Press, Philadelphia, 1986, p.131

Other possible explanations include an emphasis on obtaining adequate enforcement of existing standards, and a tendency to respond to individual grievances from union locals, which would be more likely to concern individual substances.

At a minimum, organized labor should re-examine its substance-specific legal strategy, especially if it expects to provide the leadership and vision it displayed when the OSHA Act was originally formulated. Labor's current efforts to transform the "right-to-know" into the "right-to-act" would be invigorated by the presumption rebuttal generic approach.

Because the cancer policy is diffuse in nature, there have not been identifiable advocacy groups pushing hard for its implementation. Organized labor or public

interest groups have yet to demonstrate the strength to effectively counter the AIHC on this question. The result has been a willingness to let the policy languish and to continue to muddle through. Congress has shown little desire to struggle with the complexity of risk analysis and cancer policy. Instead, it has chosen to criticize OSHA for failing to develop a more expedited rulemaking process, without offering the guidance or the authority to actually do so. The political prospects for the policy are therefore not encouraging.

The OSHA cancer policy is fundamentally a story about how newly-emerging information is used. Our society has been variously described as a "post-industrial" society, a "technologically-based" society, or a society entering the "information age." The question of applying such information is not specific to the occupational health and safety or environmental fields. Yet, the idea of specifying assumptions for areas where scientific uncertainty is prevalent, of providing classification schemes to make information comprehensible, and of providing expedited, simplified protective measures, raises the question of how our wealth of information will be used in the modern era. Will it be provided to those who need it? Will citizens and workers be educated to be able to act on it? After all, an educated populace is central to democracy. Or will information serve the needs of a relatively small elite, centered in the business and scientific communities? Several other advanced industrialized countries have chosen the latter course,[309] with reduced input by their peoples. The answer will determine in large measure whether our society can realize its full democratic potential.

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[309]See Jasanoff S: Risk Management and Political Culture, Russell Sage Foundation, New York, 1986 for an excellent comparative study on cancer policies in different industrialized nations. Also see Kelman S: Regulating American, Regulating Sweden: A Comparative Study of Occupational Health and Safety Policy, MIT Press, Cambridge, 1981 for an account of the importance of involving workers in decisionmaking.

We have been lucky with the "muddling through" approach so far. No clear cancer epidemic has emerged, and no substance has been conclusively shown to be mutagenic in subsequent generations. Of course, no one can predict whether our luck will hold. Our complex technological society demands that we graduate to a better planning process. The fact that a generic cancer policy at OSHA was formulated at all should show that we are capable of meeting the challenge.